"A CLINICAL EVALUATION OF *ADHIMADHURA MAATHIRAI* FOR *KANAKAZHICHAL* (Bacillary dysentery) IN CHILDREN"

The dissertation submitted by

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"**A **CLINICAL EVALUATION OF *ADHIMADHURA MAATHIRAI* FOR *KANAKAZHICHAL* (Bacillary dysentery) IN CHILDREN"**is a bonafide and genuine research work carried out by me under the guidance of **Dr.K.SURESH M.D(S)., Lecturer** Department of Kuzhandhai Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title previously.

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CERTIFICATE

This is to certify that this dissertation work on **"**A **CLINICAL EVALUATION OF *ADHIMADHURA MAATHIRAI* FOR *KANAKAZHICHAL* (Bacillary dysentery) IN CHILDREN"** has been carried out by **Dr.D.SARANYA**, Reg No.321314206 during the year 2013-2016 in the Department of Kuzhanthai Maruthuvam, National Institute of Siddha, Tambaram sanatorium, Chennai under my guidance and supervision in partial fulfilment of regulation laid by The Tamilnadu Dr.M.G.R Medical University, Chennai for the final M.D (Siddha), Branch IV –KUZHANTHAI MARUTHUVAM Examination to be held in OCTOBER – 2016. This dissertation work is not reprinted or reproduced from the previous dissertation work.

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CONTENTS

Introduction

1. INTRODUCTION

Siddha is one of the oldest system of medicine practiced in India. This system was developed in the state of Tamil Nadu in India. It is supposed to have been conceived by the Siddhas or evolved souls (numbering 18) who lived in the past. The word 'Siddha' comes from 'Siddhi' which means an object to be attained or perfection of heavenly bliss.

Siddhas or Siddhars were great doctors of medicine, philosophers, men with deep knowledge of anatomy and chemistry and savants noted for their wide travel, simple living and high thinking. The Siddhas have their own manuscripts or basic works, written in secret code. Some of the treasured treatises on medicine are poems in palm leaf manuscripts which are now preserved in the Saraswathi Mahal Library, Tanjavur in Tamil Nadu. They were the pioneers in the use of metals and minerals in the treatment of diseases.

The principle of Siddha medicine is on the basis of the three element theory or 'tridosha' (three humours). The three humours are Vatha (air), Pitta (bile) and Kapha (phlegm). It is believed that without these humours an individual cannot exist and imbalance of these may cause diseases. There are number of medicines in Siddha system to set right the imbalance in the three life factors.

In Siddha, diseases are diagnosed mainly with the help of signs and symptoms of diseases. Other factors that help to diagnose diseases are touch, examining the pulse, tongue, colour, speech, eyes, faeces and urine. The main aim of Siddha is to assure a healthy life to man kind.

Siddhars classified the diseases for all age groups. They treated from the baby even before birth by using herbal medicines. Siddhars mentioned many diseases

affecting childrens as a special peadiatric literature called Balavagadam or pillai pini maruthuvam.

In Balavagadam many pediatric diseases are classified based on Agakkarana noigal and Purakarana noigal. Kazhichal is one of the commonly occurring disease in infants and childrens. Among the Purakarana noigal 'Kana kazhichal' is one of the commonly occurring diseases in school going children.

The disease Kanakazhichal is characterized by mucous or blood with mucous in stool, fever, tenesmus, abdominal pain, rumbling in the intestine. It is mainly due to derangement of three dosha humour, sudden changes in weather, unsuitable foodstuffs, and chillness or from sudden fear, excitement etc.

The etiological factors, pathogenesis, clinical features of the disease explained in siddha literature are more or less related to 'Bacillary Dysentery' described in the modern system of medicine.

Kanakazhichal in children is major health hazard in the developing tropical countries like India which affects the growing children.

India is a country having larger population in the world, where people of different socio economic status are found. The poor children who lived in densely populated areas with poor sanitary facilities, lack of personal hygiene,contaminated food and water are the common cause of the disease. It is one among the major cause of morbidity in many countries in the world, So immediate care should be taken as soon as the outbreak of this disease is noticed in children.

In modern system medicine they are treating the bacillary dysentery with antibiotics, the drug having some adverse effects like damaging the intestinal mucosa, malabsorption, and decreased intestinal transit time.

The management of Kanakazhichal in Siddha system is not popularly known to the common peoples. The author would like to make awareness about the management of Kanakazhichal though Siddha medicine.

So it is essential to find out a simple herbal drug to overcome Kanakazhichal. The drug should be easily available, cost effective, easily administered and also easily palatable. Adhimadhura maathirai is found to possess the all these characters .

The drug Adhimadura mathirai is specified for Kanakazhichal in Siddha literature Balavagadam. The main ingredients of Adhimadura Mathirai like Adhimaduram, Sathikkai, Madhulam poo, having astringent and also have been found to possess an effective anti bacterial activity and seeragam have been found to be having antibacterial activity.

In this study the author would like to find out the safety and efficacy of Adhimadura Mathirai for the treatment of Kanakazhichal with the reference of Balavagadam and also trace out the various aspects of Kanakazhichal, such as etiological factors , risk factors, predisposing factors, clinical features, pathogenesis of disease and the investigations available in Siddha as well as in modern system of medicine .

Aim and Objectives

2. AIM AND OBJECTIVES

AIM:

To evaluate the clinical efficacy of ADHIMADHURA MAATHIRAI in the treatment of *KANAKAZHICHAL* (Bacillary dysentery) in children"

OBJECTIVES:

Primary objectives :

To determine the therapeutic potential and effectiveness of the drug in treating of Kanakazhichal

Secondary Objectives :

1. To collect the literary evidence on Kanakazhichal as per siddha system.
2. Clinical evaluation of the disease in the aspects of etiology , pathology, clinical features , treatment, complications and prognosis.
3. To find out the incidence of Kanakazhichal with regard to low socio-economic condition , poor hygiene, and malnutrition.
4. Study of the disease under mukkutrangal, pori pulangal, udal kattugal, neerkuri, neikuri, envagai thervugal.
5. To highlight the factors like diet, land, climate conditions and personal hygienic conditions (Unavu, Thinai, Paruva kaalangal and Ozhukkam) in the incidence of Kanakazhichal.
6. To correlate the sign and symptoms, etiological factors of Kanakazhichal with Bacillary Dysentery in the modern literature.
7. Control of the disease by creating awareness of proper hygiene.
8. Being a herbal preparation it is safe and the drug easily available.

9. To evaluate efficacy of trail medicine on Anti microbial activity by in-vitro studies
10. To evaluate Physico – chemical Analysis and Chemical analysis of trail drug.
11. To made awareness among the patients regarding this disease and its prevention.

Review of literature

3.REVIEW OF LITERATURE

3.1 SIDDHA ASPECT:

கழிச்சல்

இயல்:

உண்ட உணவு செரித்ததும் செரிக்காததுமாகவும் கழிவதும் சில வேளை கீழ்க்குடல் வெதும்பியிருப்பின் அங்கு தங்கமுடியாமையால் உடனே கழிந்துவிடும்.

உடற்கு ஊட்டம் தருவதற்காக உண்ணும் உணவு உடலில் தங்காது வெளியாகிவிடுவதும் உடலில் ஊட்டம் குறைந்து மெலிவடைவதும் உண்ட பொருள் அனைத்தும் அடிக்கடி கழிவதுமான இயல்புடையது.

Noi varum Vazhi (Etiology);

The causes for Kana Kazhical mentioned in various Siddha texts are follows,

1. Intake of the food stuffs which are easily not digestible.
2. Intake of excessive pungent and sour tested food stuffs .
3. Taking sweets, mutton and improperly cooked food stuffs .
4. Taking medicines which are having poisonous effects (Karamarundhugal)
5. Drinking impure water like sunaineer and Karachunna neer.
6. Wandering in hotsun and exposure to cold air.
7. Living in overcrowded areas.
8. Suffering from seetha suram.
9. Improper treatment from “Athisara Noi”

The above mentioned causes are stated in the following verses.

‘மானென்ற வயிற்றில் மந்தமிருக்கும் போது

மாப்பண்ட மதுரங்கள் மாங்கை கோஷ்டி

ஊனென்ற மாமிசங்கள் வேகாப்பண்டம்

உண்டதாற் கிறாணி வந்துற்பவிக்குங் கண்டாய்’

-யூகிசிந்தாமணி

தானாக உண்டாகும் விதத்தைக் கேளாய்

தரணிதனில் குளிர்ச்சியுடன் விடசத்துத்தானும்

தேனாக மிகுதினி புசித்தாலும்

திரண்ட சனக்கூட்டதில் போவதாலும்

மானான சீதசுரங் காணும் போதும்

மகத்தான இன்னொயுண்டா மென்று

கோணான நூல்தனிலே பெரியோர் சொன்னார்

கொற்றவனே யதினுடைய குந்த்தை கேளே”

- அகத்தியர் குணவாகடம்

“Gurunaadi Nool” explains the causative organism and the pathogeniesis of the disease.

‘கேளுமினிக் கிருமியால் வந்த கிரணியைத்தான்

கிருபையுடன் மூலத்திற் வேவு கொண்டு

நாளுமது கிருமியதின் குடலைச் சுற்றி

ரத்த முண்டாஞ் சுரோணிதத்தில் மலமுங்கட்டி

மீளுவது வாய்வு சென்று விரவித்தானும்

விரவியங்கே கலந்திருக்கில் கிருமியெல்லாம்

கேளுமது பலவிதமாய்க் கழியும் பாலர்

குடிகெடுத்த கிருமி செய்த கிறாணிதானே"

Due excessive heat the pathogenic microorganisms (Kirumigal)multiples in large number intestine .They make the stools dry ,decomposed and producing foul smelling gases (vayu).Then it produces Kazhical.

Murkurigunangal (Premonitory Symptoms):

- Headache
- Nausea
- Abdominal discomfort
- Burning sensation in the anus
- Tenesmus due to increased peristaltic movement are the symptoms produced in the initial stage of the disease .

Pothukurigunangal (General Signs and Symptoms):

Following the premonitory symotoms there is ,

- Passing of loose stools containing small amounts of mucus
- Pain in the abdomen
- Rumbling sounds in the intestine
- Burning sensation in the anal region
- Tenesmus

Besides passing of loose stools with mucus ,frequent scanty stools are present. During that time intense abdominal pain and rumbling sounds in the intestine is observed. Due to severe pain ,the patient will be always in sitting posture .Naadi appears week and perspiration is seen .

The above mentioned features are stated in "Siddha Maruthauvam "

நோய் எண்:

Classification of Kazhichal based on various siddha literature :

In **Balavagadam** three types of Kazhichal noigal have been described

1. Mandha kazhichal
2. Kana kazhichal
3. Seedha kazhichal

At the same time 7 types of Kazhichal noigal was explained along with treatment in Balavagadam

1. Veppu kazhichal
2. Ratha kazhichal
3. Adhisara kazhichal
4. Kaduppu kazhichal
5. Porumal kazhichal
6. Pachilai kazhichal
7. Vidaa kazhichal

In T.V Sambasivam pillai Dictionary, the following Kazhichal noigal have been mentioned

1. Seedha kazhichal
2. Ratha kazhichal
3. Sala kazhichal
4. Soba kazhichal (Diarrhoea with great weakness and exhaustion)
5. Veeludai kazhichal (white diarrhea)
6. Vayettu kazhichal(Gastrogenic diarrhea)
7. Sangara kazhichal(Diarrhea with various symptoms)

In Athma Rakshamrutham also called 'Vaidhya Saara Sangirakam' fifteen types of Kazhichal noigal have been classified

“சொல்லுகிறேன் கழிச்சல்வகை தோஷந் தன்னை

சுழிமாந்த கழிச்சலெனச் செப்பலாகும்

வெல்லுகிறேன் பாற்கழிச்சல் வரட்கழிச்சல்

வீறான வாந்தியின்றன் கழிச்சலாகும்

புல்லுகிறேன் கணகழிச்சல் மாந்தகழிச்சல்

புகழான ஆமத்தின் கழிச்சலாகும்

கொல்லுகின்ற சலகழிச்சல் வெதுப்புக்கழிச்சல்

கூறான ரத்தத்தின் கழிச்சலாமே”

”ஆமேதான் அதிசாரக் கழிச்சலாகும்

அப்பனே பொருமலின் கழிச்சலாகும்

போமேதான் சீரத்தக் கடுப்புவாகும்

பொல்லத கழிச்சலென்று நாமெய்தும்

தாமேதான் பச்சிலைக் கழிச்சலாகும்

சார்வான விடக்கழிச்சல் சாற்றலாகும்

நாமேதான் சொன்னோமே கழிச்சல் மார்க்கம்

நவின்றிட்டார் பாலருக்கு நவின்றிட்டாரே”

1. Suzhimantha kazhichal
2. Paal Kazhichal
3. Varal Kazhichal
4. Vaandhi Kazhichal
5. Kana kazhichal

6. Mandha Kazhichal
7. Aama Kazhichal
8. Sala Kazhichal
9. Vethuppu Kazhichal
10 Ratha Kazhichal
11. Adhisara Kazhichal
12.Porumai Kazhichal
13.Ratha kaduppu
14.Pachilai Kazhichal
15.Vida Kazhichal

Two types of Kazhichal have been described in Pararasa sekaram balaroga Nithanam,

1. Vayitru Kaduppu
2. Vayitrulaivu

In Jeeva Rakshamrutham the following Kazhichal noigal are given,

1. Ratha Kazhichal
2. Sala Kazhichal

In Noi Nithanangal, ten types of kazhichal noigal are given,

1. Moola Kazhichal
2. Vatha Kazhichal
3. Pitha Kazhichal
4. Seetha Kazhichal
5. Vatha pitha Kiraani
6. Pitha Silethuma Kiraani
7. Vatha Seetha Kiraani

8. Thondha Kiraani
9. Vayitru Kaduppu
10. Vayitru Kodhippu

According to Agathiyar Vaidhya Kaaviyam 1500, Kazhichal is classified into six types,

“கழிச்சலென்ற கிராணியிலே விதமாறப்பா

கண்ட பித்தம் அனல் வாதம் வாயுவாகும்

அழிச்சலென்ற ஐயநீர் மூன்றுங்கூடி

அப்பனே பேதிக்கும் பலந்தான் போகும்

தொழிச்சலென்ற வாயுதான் மேகபேதி

திறமான மூலத்தின் தோடபேதி

பழிச்சலென்ற சங்கான பேதியொன்று

பாரப்பா வாயுவொன்று ஆறுமாச்சே”

1. Vatha Kazhical
2. Pittha Kazhical
3. Kabha Kazhical
4. Moola Kazhical
5. Sangana Kazhical
6. Mega Kazhical

Same classification has given in Thirumoolar Vaidhyam” Karukkidal 600.

கழிச்சல் கிராணி காணும் விதம் கேளும்

அழிச்சிய பித்த மணல் வாத மையமாம்

செழுச்சிய வாயு சேர்ந்தவை மூன்றாலே

பழிச்சென பேதிக்கும் பார் பெலம் போகுமே"

"பெலமான மேகத்தின் பிறந்ததொறு பேதி

குலமான மூலத்தின் கொடியதொரு பேதி

சுகமான வாயுவாற் சங்த்தொரு பேதி

வுலமானதாறும் வகுத்த முறையாமே"

கணக்கழிச்சல்:

"சீதங் கழியு மலங்கழியும் திரும்பிக் கெட்ட பால்போலே

போதக் கழியுங் கறித்தண்ணீர் போலுங் கையுங் கால்குளிர்ந்து

காதை யடைக்கும் வெதுப்புண்டாம் கையிற் பிள்ளை தங்காது

கோதா யிந்தக் கணங்கண்டால் குலவு மிதன்பேர் கழிகணமே"

- பாலவாகடம்

சீதமாக கழியும் அல்லது மலமாக கழியும், இவ்விதமின்றி கெட்டுப்போன பால் போலவும் கழியும், கரித்தண்ணீர் போலவும் கழியும், கைகால் குளிர்ந்து இருக்கும்.காது அடைக்கும், சுரம் காயும், பிள்ளை கையில் தங்காது போன்ற குறிகுணங்கல் காணப்படும்.

Patient have gripping pain in the abdomen ,with irritation in and around the anal region, rectal tenesmus with loose stools , poor appetite and weakness of the body due to excessive loose stools .

The same features have been described in Agathiyar 2000

”இடுப்புக் கடுத்து வயிறுளைந்து இளகுச் சிதமாற்றீந்து

முடுகக்குத்தி முக்கி துயரமுமாய் உண்ணா மலமே கழிந்தடங்கும்

அடுத்தோரன்னந்தன்னை தேடா தறவே மெலிந்து வருந்தொடுக்கும்

வயிற்றுக்கடுப்பென்று சொன்னோந்த் செய்யும் துயர்கண்டே”

- அகத்தியர் 2000

Patient having fever with abdominal pain, loss of appetite ,loose motion with mucus, general weakness and shivering .

Mukkutra Verupadugal(Pathology):

According to siddha system of medicine ,diseases are produced due to derangements in Thridoshas (i.e) Vatham ,Pitham,Kabam.

The siddha concepts of pathology of Kanakazhichal have been described in “ Thirumoolar karukkidai 600.

‘கழிச்சல் கிராணி காணும் விதம்கேளு

அழிச்சிய பித்தம் அலைவாதம் ஐயமாம்

செழுச்சிய வாயு சேர்ந்தவை மூன்றால்

பழிச்சென பேதிக்கும் பார் பெலம் போகுமே

- திருமூலர் கருக்கிடை 600

In Kanakazhichal due to various causes stated above , the pitha kuttram is vitated from its normal condition. This in turn stimulates Abanan ,a type Vatha . Also saaram are affected.

Vitated pitham along with Kabam causes passage of loose stools with mucus.

Pain in the abdomen and tenesmus are produced mainly due to vitiated Vayu.

Finally all the Trithathus are deranged from their normal positions and produces “Muppini noi”

Piniyari muraimai (Diagnosis):

In siddha system of medicine , diagnosis of a disease is made up on the following principles,

1. Poriyaalarithal (Inspection)
2. Pulanaalarithal(Interrogation)
3. Vinaadhal(palpation)

Pori are the Five organs of perception namely nose, ears, tongue, skin, and eyes.

Pulan are the five objects of senses namely smell,sound, taste, sensation, and sight.

Poriyaalarithal and pulanaalarithal goes hand in hand with concept of examining the patients pori and pulan with that of the physician’s pulan and pori.

By Vinaathal , the physician knows about the patients name, age, native place, socio economic status, family history dietic habits etc. If it is infants or child or unable to talk (deaf and dumb) the particulars are obtained from his/her relatives or parents (informer).

Poriyaalarithal, pulanaalarithal and vinaadhal are effected through Envagai thervugal.

Envagai Thervugal:

Envagai Thervugal is considered to be physicians instruments.

”நாடி பரிசம் நா நிறம் மொழி விழி

மலம் மூத்திரமிவை மருத்துவராயுதம்”

1. Naadi(pulse)
2. Sparisam(Palpation)
3. Naa(Tongue)
4. Niram(Colour of skin)
5. Mozhi(speech)
6. Vizhi(Eyes)
7. Malam(stools)
8. Moothiram(Urine)

Naadi(Pulse):

Naadi is an important observation for diagnosis and prognosis.Naadi is responsible for the existence of life and can be felt one inch below the wrist on the radial side by means of palpation with the tips of index, middle, and ring finger corresponding to vadham, pitham and kabam.

Normally the three humors vadham, pitham and kabam exist in the ratio 1: ½:1/4.

Derangement in these ratio leads to various disease is best diagnosed by feeling the naadi.

Naadi nadai in KanaKazhichal:

"தொந்தித்த சிலேற்பனத்தில் வாய்வு கூடித்

துடர்ந்த குன்மம் நெஞ்சடைப்பு சுவாசகாசம்

வந்தித்த குரல் தனிலே வுறுத்தலீளை

வழுவழுப்பு நீரூறல் மலத்தில் சீதம்

வெந்திரதம் கொழுத்தல் குத்துத் திமிர்வியாதி

வீச்சுடனே வலியெட்டுண்ட் திரட்சை பாண்டு

அந்தித்த குறுகுறுப்பு மயக்கம் விக்கல்

ஆனபல பிணியும் வந்தடறுந்த் தானே”

Thondhamana Kabam with Vaayu produces motion mixed with mucus.

Naadi Nadai for kiraani may also responsible for’KanaKazhichal’

”சிறப்பான பித்ததில் வாத நாடி

சேரிலுறுந்த் தாது நட்டமுதர பீடை

உறைப்பாகச் செரியாமைக்குன் மஞ்சூலை

யுற்ற சுரங்கிராணி வயிற்றிரைச்சல் மந்தம்

அறைப்பான ஓங்கார புறனீற்க்கோவை

ஆயாச மிரக்க மொடு மயக்க மூர்ச்சை

முறைகாய்வு விஷ வீக்கம் மூலவாய்வு

முரடான நோய் பலவுமுடுகும் பண்பே”

In pitha vatham kiraani is produced.

When there is aggravated vatha naadi the disease kiraani is produced

’’வாதமெனும் நாடியது தோன்றில் வெப்பு

சீதமந்தமொடு வயிறு பொறுமல் திறட்சி வாயு

சீதமுறுங்கிறாணி மகோதரம் நீராமை

திரள்வாய்வு சூலை வலிகடுப்பு தீரை

நீதமுருங் கிருமிகுன்மம் அண்டவாதம்

நிலையும் நீர்கிரிச்சரங்கள் தந்து மேகம்

பேதகமா முதரபிணி மூலரோகம்

பேச வெகுபிணிகளுமே பொருளதாமே

Naa(Tongue) :

In the examination of tongue ,colour, coating wetness or dryness ,deviation ,fissures. Variation in taste, condition of teeth and gums are carefully noted.

In Kana Kazhichal coated tongue shows indigestion and loss of appetite and sometimes pallor may be noted.

Niram(colour):

Colours indicating vatham, pitham kabam and thridhodas .Other than siddha concept cyanosis, pallor, yellowish, discolouration of the body is present.

In Kana Kazhichal no colour changes in the body.

Mozhi(Speech):

In the examination of mozhi , the pitch of voice (high or low), laughing, slurring, speech in hallucination , crying, breathlessness or wheezing and incompleteness while talking may be noted.

In KanaKazhichal mozhi may not be affected.

Vizhi(Eyes):

Both sensory and motor disturbances are noted.Colour, inflammation, ulceration, sharpness of vision, lacrimation, response of pupil to light may also be noted.

In KanaKazhichal pallor of eyes sometimes may be noted.

Sparisam(Skin):

By sparisam , the temperature of skin (heat or cold), smoothness, roughness, hardness, sweat, dryness, swelling, tenderness,ulcers, and pigmentation can be examined

In Kana Kazhichal some times raised body temperature may be present.

Malam(faeces):

In the examination of malam , Niram(colour), Nurai(froth), Erugal(solid), Elagal(Semi solid or liquid), quantity(increased or decreased), smell can be noted. Other examinations like diarrhea,presence of blood or mucus or undigested matter in stools and odour can also be noted.

In KanaKazhichal the malam is liquid or semisolid, large or scanty in quantity, greenish or brick red or dark brown in colour, sometimes it gives offensive odour containing blood or mucus.

Moothiram(Urine):

In the examination of urine, colour, odour, quantity of urine, the presaence of froth, deposits, blood, and pus abnormal constituents such as sugar, protein etc.frequency of urination can be noted.

In KanaKazhichal the quantity of urination may be slightly deminished.

Neerkuri:

'வந்த நீர்க் கரியெடை மனம் நுரை எஞ்சலென

றைந்திய லுளவை யறைகுது முறையே'

-சித்த மருத்துவாங்க சுருக்கம்

According to this verse, the general features of urine are niram,edai, manam, nurai, enjal.

- Niram indicates the colour of the urine voided.
- Edai indicates the specific gravity of the urine.
- Manam indicates the smell of urine voided.
- Nurai indicates the frothy nature of urine voided.
- Enjal indicates the quantity of urine.

Collection of urine for Neikuri:

”அருந்துமா றிரதமும் அவிரோத மதாய்

அக்கல் அலர்தல் அகாலவூண் தவிற்ந்தழற்

குற்றளவருந்தி உறங்கி வைகறை

ஆடிக்கலசத் தாவியே காது பெய்

தொருமுகூர்த்தக் கலைகுட்படு நீரின்

நிறக்குறி நெய்க்குறி நிருமித்தல் கடனே”

Prior of the day of examination, the patient is asked to take a regular and balanced diet without any derangement in amount and quality.The patient is allowed to have a good sleep. In the next day early morning , the first voided urine is collected in a glass container for analysis.

The analysis should be carried out in one and half hours.A drop of gingelly oil is dropped into a wide vessel containing the urine and is kept in the bright light in a calm palace without shaking.The derangements of three thathus is studied by nture of oil on the surface of urine.

‘அரெவென நீண்டிடின் அஃதுவே வாதம்

ஆழிபோற் பரவின் அஃதுவெ பித்தம்

முத்தொத்து நிற்கின் அஃதுவெ கபம்’

Oil spreading like snake indicates Vadham

Oil spreading like ring indicates Pitham

Oil floating as pearl like indicates kabam

In KanaKazhichal oil spreads like a snake or pearl indicating of vaadham and kabam.

Complications:

If the above diseases are associated with kiraani it may leads to a fatal outcome.

"பாண்டு பிரமேகம் பின்வாத சூலைகுன்மம்

வேண்டா ஷயஞ்சன்னி வெண்சோபை-னீண்ட

அதினீரே காமாலை யானபிணி தம்மு

நதிசாரமா காதறி"

-கண்ணுசாமியம்

"சன்னியதி சாரஞ் சாருங் கிராணி குன்மம்

உன்னிய சயகாசம் உட்காய்ச்சல் -துன்னியே

போக்கும் விடசோபை பொல்லாத நீரிழிவில்

வீக்கங் கூடாதென வில்"

-கண்ணூசாமியம்

"சன்னி விடசோபைசார் குன்மம் நீரிழிவு

துன்னுங் கிராணி சுரம் பேதி பன்னுபிர

மேகம் சயமிவரற்றுள் மூச்சு விக்கல் மேல்வீக்கம்

ஆகிலுயிர் போமறி"

-கண்ணூசாமியம்

If the kiraani is associated with Dropsy, hiccup, dyspnoea, it would be fatal.

"உண்டாகும் பேதிதான் உக்கிரமாய்க் கண்டால்

உத்தமனே குடலுக்குள் துவாரங் கண்டு

நன்றான குடல் சவ்வுத் தாபிதமே கண்டு

நிலமான ஏரலில் தான் சீக்கட்டி கொள்ளும்

பண்டான இரணமுலர்ந்து குடற்சுருங்கி நாக்கால்

பளிச்சென்று மலபந்தம் உண்டா மப்பா

சிண்டான சிலேட்டுமச் சவ்வு அழுகிப்போனால்

சிறப்புடனே சுரப்புக் கண்டு இறப்பான் தானே"

From the above verses , it is clear that severe bethi leads to perforation and inflammation of the colon, Liver abscess, constipation and obstructions.Sometimes it may ends fatally.

Prognosis:

Kana Kazhichal is a curable one with proper medicine at proper time.If it is not treated with proper medicine, it leads to severe discomfort, ulceration of colon causing passage of excessive amount of stools with mucus, Pulse appears weak,perspiration is seen.Eyes become sunken and dryness of tongue.Finally sometimes it may ends in fatal condition(Shanmugavelu 1988, kuppusamy mudhaliyar1987).

Differential Diagnosis:

மாந்த கழிச்சல்:

"வாந்தி பிராந்தி மூர்ச்சையதாய் வாய்ந்து குரலுஞ் சீணித்து

காய்ந்து மேனி வெதுவெதுப்பாய்க் கைகால் குளிர்ந்து வலியுண்டாம்

சேர்ந்து கழியு மலந்தானும் சீர்கெட்டிருக்கும் பலவிதமாய்

போந்த மாந்தக் கழிச்சலிது பொல்லாதெனவே புகன்றெனரே"

-பாலவாகடம்

வாந்தி, மயக்கம், மூர்ச்சை, குரல்கம்மல், உடல் காய்ந்து வெதுவெதுத்தல், கைகால் குளிர்ந்திருத்தல், வலித்தல், மலம் செர்ந்திருந்து பல விதமாக கழிதல்,குழந்தை சரியான நிலையிலாமற் பலவித துன்பத்தை அடைதல் ஆகிய குறிகுணங்கள் காணும்.இது மிக கொடியதாகும்.

ஆமக் கழிச்சல்:

”உண்ட பாலெதிரெடுக்கும் உடல்பல முழக்கங் காட்டும்
கண்டுமே ரத்தஞ் சாலச் சுரமிகுந்த் திருக்கு மேனி
கண்டுசேர் மொழியுந்த் தாழ்ந்து ந்காலொடு கையுனீத்து
விண்டிடி லாம மென்று விளம்பினர் முனிவர் தானே”

உண்டபின் பால் எதிரெடுத்து வாயாலெடுக்கும், உடல் அதிகமாக மாறுதலடையும்.உடலில் செந்தீர் மிக சுண்டும்.சுரம் அதிகமாகும்.குரல் தாழ்வடையும். கை கால் அசைவற்று கிடக்கும்.இவை ஆமக்கழிச்சலின் குணங்கள் ஆகும்..

வயிற்றுளைவு:

”வந்திடும் வெதுப்புக்காயும் வயிறுளைந்திடுதீன்செல்லால்
துரத்திடு முறங்க வொட்டாதுள மலங்கழிந்து சோறும்
பொருத்தொலாங் கழலும் புன்போற் பொருக்கொணா நடுகங்கூறல்
பொருத்திடுங் கழிச்சல்சீதம் வெறுவயிற்றுளைவிதாமே”

Increased body temperature, abdominal cramps, pain present in all major joints,shivering followed by frequent loose stools may also be observed in Vayittru Ulaivu

KanaKazhichal should also be differentiate from vadha Kazhichal, pitha Kazhichal, kaba kazhichal, mukkutra kazhichal and oozhi noi.

Maruthuvam:

'மூன்றிலொன்று யர்ந்ததை முன்னரறிந்து

முந்தியதனை யொழித்திடு மருந்திடு

தணியும் நோயின் தந்திரமிதுவே

பேணிக் கணித்திடின் பிறவாய் பின் குணம்"

In Siddha system of medicine, the principle of treatment bringing back the vitiated thathus to their normal position.

Line of Treatment:

1. In the disease KanaKazhichal , the vitiated Kaba kutram and keelnokku kaal (abanan) should be brought to their normal positions.
2. Specific medicine for arresting the passage of loose stools with blood or mucous.
3. A large number of medicines are started in different literatures. Among them an economical and efficacious medicine is 'Adhimadhura Maathirai'.It is administered with hot water two times a day.

Diet Regimen:

Cow's butter milk , buffalo's butter milk and goat's milk are useful in Kana Kazhichal .

'வீக்க மகோதர முள் வீறுகுன்மம் பாண்டு பித்தந்த்

தாக்கு மருந்திட்ட திதிசாரமோடு - கூக்குரலே

மாறத் திரிதோஷ மந்த மணற்றாகம்போம்

விறாவின் மோறுக்கு மெய்'

-பதார்த்த குணசிந்தாமணி

'தாகங் கிராணி கலக்கழிச்சல் காமாலை

ஆகங் குடை புழுவு மற்றுப்போ-மோகமில்லாத்

தேவாமிர்த முமாஞ் சீர் மானிடர் தமக்கு

மூவாமருந்தெருமை மோர்'

-பதார்த்த குணசிந்தாமணி

'வெள்ளாட்டுப் பாலுக்கு மேவிய நற்றீபனமாந்த்

தள்ளாடு வாத பித்தஞ் சாந்தமாம்-உள்ளிரைப்புச்

சீதமதிசாரஞ் சிலேஷ்ம மறும் புண்ணாறும்

வாத கிலேசமும் போமாய்ந்து'

-பதார்த்த குணசிந்தாமணி

'வறகு சோறுட நல்லெண்ணெய் வைத்த நீர்ச் சோறு மோரும்

தரமிகு மிரச வாழை தாங்கிய கனியு நன்றாம்

புரமிகு முசுட்டைக்கீரை பொருந்திய கறியுனன்றாம்

ஊரமிகு மோருங்கூடி யுண்டிடி லுளைவு போமே'

பரராச சேகரம் பாலரோகநிதானம்

பத்தியம்:

'நெற்பொரியைத் திண்றால் நெடுந்தாகம் வாந்தி மந்தம்

மற்பித்தம் வாத மத மூர்ச்சை-பற்பலவாம்

பேதியருசியிவை பேருலகை விட்டொழியும்

சாதிமட மயிலே சாற்று'

-குணபாடம் மூலிகை வகுப்பு

Nerpori is useful for to reduce thirst,nausea and vomiting in dysentery mainly useful in KanaKazhichal if dehydration may be present.

காராமணிக் கீரை காட்டுப் பறங்கியிலை

பேராம் பெரும் பயற்றின் பேரிலைகள்- சீரார்

அகத்தியருங் கத்தரிக்காய் ஆயிழையே மீன்கள்

பகைத்ததிக்க பேதிதரும் பார்'

- பதார்த்த குண சிந்தாமணி

காராமணிக்கீரை, காட்டு பறங்கியிலை, பெரும்பயறு இலை, அகத்திக் கீரை, கத்தரிக்காய், மீன்கள் ஆகிய பொருட்களை நீக்க வேண்டும்.

3.2 MODERN ASPECT:

Dysentery can have a number of causes. Bacterial infections are by far the most common causes of dysentery**.** These infections include Shigella, Campylobacter, E.coli, and Salmonella species of bacteria. The frequency of each pathogen varies considerably in different regions of the world. For example, shigellosis is most common in Latin America while Campylobacter is the dominant bacteria in Southeast Asia. Dysentery is rarely caused by chemical irritants or by intestinal worms.

Dysentery is an acute inflammation of the large intestine characterized by passing loose stools with blood and mucous or mucous in the stools.

Dysentery results from entero invasive micro organisms penetrate through the mucousa and cause inflammation of intestinal wall, bacteria, fungi and protozoa

There are two main types of dysentery. The first type, amoebic dysentery or intestinal amoebiasis, is caused by a single-celled, microscopic parasite living in the large bowel. The second type, bacillary dysentery, is caused by invasive bacteria. Both kinds of dysentery occur mostly in hot countries. Poor hygiene and sanitation increase the risk of dysentery by spreading the parasite or bacteria that cause it through food or water contaminated from infected human feces.

Bacillary dysentery is a type of dysentery, and is a severe form of shigellosis.

Bacillary dysentery is associated with species of bacteria from the Enterobacteriaceae family. The term is usually restricted to Shigella infections.

Shigellosis is caused by one of several types of Shigella bacteria. Three species are associated with bacillary dysentery: Shigella sonnei, Shigella flexneri and Shigella dysenteriae.A study in China indicated that Shigella flexneri was the most commonserotype.

Salmonellosis caused by Salmonella enterica (serovar Typhimurium) has also been described as a cause of bacillary dysentery, though this definition is less common. It is sometimes listed as an explicit differential diagnosis of bacillary dysentery, as opposed to a cause.

Bacillary dysentery should not be confused with diarrhea caused by a bacterial infection. One characteristic of bacillary dysentery is blood in stool,which is the result of invasion of the mucosa by the pathogens.

BACILLARY DYSENTERY:

Bacillary dysentery is an acute infection of the bowel caused by the organisms belonging to the genus shigella.This disease is more common in infants than in adults.

Shigella is nonmotile , gram negative bacilli belonging to the family Enterobacteriaceae and consists of four main pathogenic groups.

1.S.dysenteriae(Group A)

2.S.Flexneri(Group B)

3.S.Boydii(Group C)

4.S.Sonnei(Group D)

The genus is characterized by its ability to invade the intestinal epithelial cells and to produce highly potent toxins that irreversibly inhibit eukaryotic cells protein synthesis by a specific enzyme action.

Epidemiology:

Bacillary dysentery is endemic all over the world. It occurs in epidemic form wherever there is a crowded population with poor sanitation. Epidemics in civilian communities are associated with poverty.

Infection with shigella occurs most often during summer and during rainy seasons in tropical climates.Both sexes are equally affected and in endemic among school going children in tropical countries. It is most common in poor hygienic places.

S.dysenteriae occurred in south India in the years 1974-78 and in the eastern parts of India and Bangladesh in mid 1980.

Mode of transmission:

The only sources of infection are human beings .The mode of transmission may be as follows;

1. Direct through contaminated finger hands to mouth infection (Faeco oral route.
2. Through contaminatd water and food or drinks.
3. Through fomites such as door handles, water tapes, lavatory seats.
4. Through flies which may transmit the infection as mechanical vectors.
5. Though contaminated water when used to irrigate or wash vegetables.
6. The spread is boosted by the low level of personal hygiene and environmental sanitation level.

Pathogenesis:

Transmission is fecal-oral and is remarkable for the small number of organisms that may cause disease (10 ingested organisms cause illness in 10% of volunteers, and 500 organisms cause disease in 50% of volunteers). Shigella bacteria invade the intestinal mucosal cells but do not usually go beyond the lamina propria. Dysentery is caused when the bacteria escape the epithelial cell phagolysosome, multiply within the cytoplasm, and destroy host cells. Shiga toxin causes hemorrhagic colitis and hemolytic-uremic syndrome by damaging endothelial cells in the microvasculature of the colon and the glomeruli, respectively. In addition, chronic arthritis secondary to S. flexneri infection, called reactive arthritis, may be caused by

a bacterial antigen; the occurrence of this syndrome is strongly linked to HLA-B27 genotype, but the immunologic basis of this reaction is not understood.

Infection occurs by ingestion.The minimum infective dose is low as few as 10,000 bacilli being capable of initiating the disease probably because they survive gastric acidity better than other enterobacteria.Their pathogenic mechanisms resemble those of Enteroinvasive E.coli.

Bactremia may occur on severe infections, particularly in malnourished children

Morphology:

In severe bacillary dysentery the colonic mucosa becomes hyperemic and edematous, enlargement of lymphoid follicles creates small projection nodules.Within the course of 24 hours , fibro suppurative exudates first patchily then diffusely covers the mucosa and produces a dirty grey yellow pseudo membrane.

The inflammatory reaction within the intestinal mucosa builds up the mucosa becomes soft and friable and irregular superficial ulcerations appear.

Histologically, there is predominantly mononuclear leukocytic infiltrate within the lamina propria ,but the surfaces of the ulcers are covered with an acute, suppurative, neutropilic reaction accompanied by congestion , marked edema , fibrin deposition and thrombosis of small vessels.

Incubation period:

The incubation period is generally between 2-7 days.

Clinical features:

After ingestion of shigella there is an incubation period of several days before symptoms. Characteristically severe abdominal pain, fever, anorexia, passing mucoid consistency of loose stools occurs.

The stools may be watery or mucoid large volume initially evolving into frequent mucous stools.Physical examination may show abdominal distension and tenderness,hyperactive bowel sounds and tender rectum on digital examination.Chronic diarrhea is uncommon except in malnourished infants.Only about 10% patients have diarrhea persisting for more than 10days.

Neurological findings are among the most common extra intestinal manifestation of bacillary dysentery occurring in 40% of hospitalized infected children.

They are,

- Convulsion
- Lethargy
- Headache
- Confusion
- Nuchal rigidity
- Hallucination

The causes of neurological findings are not known. Hypocalcemia and hyponatraemia may be associated with seizures in a small number of patients. Most important complication is dehydration with its attention risk of renal failure and death.

Symptoms and Complications:

The main symptom of dysentery is frequent near-liquid diarrhea flecked with blood, mucus, or pus**.** Other symptoms include:

- Sudden onset of fever and chills
- Abdominal pain
- Cramps and bloating
- Flatulence (passing gas)

- Urgency to pass stool
- Feeling of incomplete emptying
- Loss of appetite
- Weight loss
- Headache
- Fatigue
- Vomiting

Other symptoms may be intermittent and may include recurring low fevers, abdominal cramps, increased gas, and milder and firmer diarrhea. You may feel weak and anemic, or lose weight over a prolonged period (emaciation).

Mild cases of bacillary dysentery may last 4 to 8 days, while severe cases may last 3 to 6 weeks. Amoebiasis usually lasts about 2 weeks.

Bacillary dysentery symptoms begin within 2 to 10 days of infection. In children, the illness starts with fever, nausea, vomiting, abdominal cramps, and dysentery. Episodes of diarrhea may increase to as much as once an hour with blood or mucus in the child's stool. Vomiting may result in rapid and severe dehydration, which may lead to shock and death if not treated. Signs of dehydration include an extremely dry mouth, sunken eyes, and poor skin tone. Children and infants will be thirsty, restless, irritable, and possibly lethargic. Children may also have sunken eyes and may not be able to produce tears or urine, the latter appearing very dark and concentrated.

Diagnosis:

Essentials of diagnosis:

- Abdominal pain with loose mucoid stools
- Fever

- Peripheral blood leucocytosis
- Stool culture

Prevention:

As bacillary dysentery is exclusively human infection transmitted by feceo oral route, control consists essentially in improving environmental sanitation.Health education with an emphysis on washing hands with soap after each defecation is important.

Decontamination of water supplies , use of sanitary latrines, protection of food preparation and its storage can all reduce the primary and secondary transmission of shigella.

Breast feeding decreses the risk of symptomatic shigellosis and its severity in infants who acquire infection despite breast feeding.

- Eradication of vectors such as houseflies. Hygienic practices such as keeping food covered filtration and boiling water etc.
- Since chlorination of water in effective iodine realizing tablets, Globaline tablets are convenient and effective.
- Avoiding consumption of raw vegetables can reduce the incidence of amoebiasis.
- Those cooking for large number of people must periodically undergo stool examinations for detecting asymptomatic cyst passers who are the reservoirs of infection.
- Proper sanitary disposal of human excreta.
- Maintaining good personal hygiene like hand washing with soap after defacation.These factors are effective in the prevention of disease.

Drug review

3.3 DRUG REVIEW:

1. அதிமதுரம்: *Glycyrrhiza glabra*

Family: Fabaceae(Papilionaceae)

பயன்படும் உறுப்பு: வேர்

சுவை: இலை-இனிப்பு, கைப்பு; தன்மை-வெப்பம்; பிரிவு-கார்ப்பு

வேர்-இனிப்பு; தன்மை-சீதம்; பிரிவு-இனிப்பு

செய்கை :

வறட்சியகற்றி

உள்ளழலாற்றி

கோழையகற்றி

மலமிளக்கி

உரமாக்கி

குணம் :

"கத்தியரி முப்பிணியால் வருபுண் தாகங்

கண்ணோயுன் மாதம்விக்கல் வலிவெண் குட்டம்

பித்தமெலும் புருக்கி கிரிச்சரம் ஆவர்த்த

பித்தமத மூர்ச்சை விடபாகம் வெப்பந்த்

தத்திவரு வாதசோ நிதங்கா மாலை

சருவவிடங் காமியனோய் தாதுனட்டங்

குத்திருமல் ஆசியங்ம் இதழ்னோய் இந்து

குயப்புனும்போம் மதூகமெனக் கூறுங் காலே"

உடல் அனல் தனிய அதிமதுரம் 17 கிராம் எடுத்து ,காய்ந்த நீரில் அரைத்து கலக்கி, வடிகட்டி காலை மாலை கொடுக்கலாம்.

Chemical constituents:

Glycerrhizin is isolated from the root is the principal sweetening constituent. Glycyrrhizic, and Glycyrrhetinic acids, liquiritin,isoliquiritin,neoisoliquiritin, liquiritigenin, isoliquiretigenin, Rhamnoliquiritin, Glabrin, Glabranin,Formononetin. A and B hispaglabridin, Licoricidine and Liquiridiolic acids.

The characteristic aroma of the volatile oil of liquorice is due to the presence of a mixure of estragole, anethole, eugenol, indole, y-nonalactone, and cumic alcohol.

Properties and Uses:

Root extract is good for gastric ulcer, decoction of roots recommended to prevent graying hair

Pharmacological activity:

Antimicrobial activity,antibacterial activity, anti inflammatory activity.

2.சீரகம்: ***Cuminum cyminum***

Family:Apiaceae(Umbellifere)

பயன்படும் உறுப்பு: விதை

சுவை-கார்ப்பு, இனிப்பு; தன்மை-தட்பம்; பிரிவு-இனிப்பு

செய்கை:

அகட்டுவாயகற்றி

வெப்பமுண்டாக்கி

பசித்தீத்தூண்டி

துவர்ப்பி

குணம்:

”பித்தமெனு மந்திரியைப் பின்னப் படுத்தியவன்

சத்துருவை யுந்துறந்து சாதித்து -மத்தனெனும்

ராசனயு மீவென்று ந்ண்பைப் பலப்படுத்தி

போசனகு டாரிசெயும் போர்”

சீரகத்தை சுண்ணம்பு நீர் விட்டு கலந்து சிறிது ஊறிய பின் முறத்திலிட்டு தேய்த்துப் புடைத்துலர்த்திப் பழரசம் விட்டரைத்து, அரசிலையில் வைத்து வேகவைத்து ஆறவிட்டு மறுபடியும் இப்படியே செய்து கொடுக்க சிறு குழந்தைகளுக்கு உண்டாகும் கழிச்சல் தீரும்.

பஞ்சதீபாக்கினி லேகியம் பாக்களவு உண்டுவர குத்துவலி, கடுப்பு,கழிச்சல் பொருமல், நிணகழிச்சல் தீரும்

சிறிது சீரகத்துடன், இரண்டு வெற்றிலை, நான்கு நல்ல மிளகு சேர்த்து மென்று தின்று ஒரு டம்ளர் குளிர்ந்த நீர் பருகினால் வயிற்றுப் பொருமல் வற்றி நலம் பயக்கும்.

சீரகத்துடன், மூன்று பற்கள் பூண்டு வைத்து மைய அரைத்து எலுமிச்சை சாறில் கலந்து குடித்தால் குடல் கோளாறுகள் குணமாகும்.

ஓமத்துடன் சிறிது சீரகம் இட்டு கஷாயம் செய்து சாப்பிட்டால் அதிக

பேதி போக்கு நிற்கும்

Chemical constituents:

Fruits contain apigenin-7-0-glucoside and luteolin-7-0-glucosides as essential oil and fixed oil and fixed oil, cumin and flavonoids are chief constituents.

The characteristic odour of cumin oil is attributed to the presence of Cyminaldehyde, 1,3-p-menthadien-7-al, and 1,4-p-menthadien-7-al.

Properties and Uses:

Fruits are astringent, digestive, aphrodisiac, constipating, stomachic, Revulsive , uterine and nervine tonic.

Useful in dyspepsia, chronic diarrhea, fever, flatulence, vomiting and hemorrhoids.

Pharmacological Activity:

Antimicrobial activity,Antifungal activity, Anticytotoxic activity, Antiviral activity,Dermatophytic.

3.அதிவிடயம்: *Aconitum heterophyllum*

Family: Rananculaceae

பயன்படும் உறுப்பு: வேர்

சுவை: கைப்பு; தன்மை-வெப்பம்; பிரிவு-கார்ப்பு

செய்கை:

பசித்தீத்தூண்டி

துவர்ப்பி

வெப்பகற்றி

ஆண்மைப்பெருக்கி

உரமாக்கி

முறைவெப்பகற்றி

குணம்:

அதிவி டயம்சர்க்க ராற்புதனோய் வெப்பு

கொதிமருவு பேதியோடு கோழை-எதிர்வாந்தி

என்றுரைக்கும் நோய்க்கூட்டம் இல்லா தகற்றிவிடும்

குன்றை நிகர்முலையாய் கூறு"

இது புண், முறைசுரம், பெருங்கழிச்சல், கோழை, மேல் நோக்கிய வாந்தி முதலிய நோய்கலைப்போக்கும்.

கழிச்சலுடன் கூடிய சுரத்திற்கு அதிவிடயம், சுக்கு, குடசப்பாலப்பட்டை, முத்தக்காசு, சீந்தில்கொடி இவையனைத்தும் வகைக்கு ஒன்றேகால் வராகனெடை தூக்கி உலக்கு நீரில் சிதைத்துப்போட்டு நாலில் ஒன்றாக சுருக்கி அதை இரண்டு அல்லது மூன்று பாகமாக பிரித்து ஒரு நாளில் கொடுக்கலாம்.

Chemical constituents:

Diterpenoid alkaloid Atisine is the main constituent of the root.

Atidine, Histisine, Hetisine, Heterophyllacine, Heterophylline, Heterlophylline, Isoatisine, Dihydroatisine, Hetisinone and Benzoyl heteratisine.

Properties and Uses:

The root is used in the treatment of hysteria and throat diseases.It is considered astringent and prescribed in diarrhea, especially in infants and for dyspepsia, vomiting and cough.The root is efficacious for irritability of stomach and in abdominal pains (Nadkarni,1954;chopra et al.,1956; wealth of India,1985)

The roots are highly recommended for diseases in children.They are useful in dysentery, diarrhea, stomach disorders ,Internal inflammatory conditions in children

The roots are acrid, bitter, thermogenic, expectorant, stomachic, alexeteric, digestive, antiperiodic and tonic.

Ethnobotanical studies:

The plant find used in diarrhea, intestinal parasites, ascites, fever. As tonic used in dysentery and inflammation.

The roots are used in fever, stomach troubles, vomiting, cough, diarrhea.

Rhizome is astringent, tonic, stomachic, used in infant fever and diarrhea, dysentery, cough(Singh and Aswal,1992)

Pharmacological Activity:

Anti inflammatory activity, Antioxidant, Anti fungal activity,Anti secretary& anti motitity activity, Hypolipidimic activity.

4.மாதுளை-*Punica granatum*

பயன்படும் உறுப்பு: பூ, பிஞ்சு, பழம், விதை, பட்டை

சுவை:

பூ, பழத்தோல், பட்டை:- துவர்ப்பு; தன்மை-தட்பம்; பிரிவு-கார்ப்பு

பழம்,விதை: இனிப்பு; தன்மை-தட்பம்; பிரிவு-இனிப்பு

செய்கை:

பொது : துவர்ப்பி

குருதிப்பெருக்கி

பூ, பழத்தோல்: துவர்ப்பி

பசித்தீத்தூண்டி

மரப்பட்டை, வேர்ப்பட்டை;

கிருமினாசினி

புழுக்கொல்லி

பழம்: குளிர்ச்சியுண்டாக்கி

விதை: துவர்ப்பி

புழுக்கொல்லி

சாயமேற்றி

ஆண்மைப்பெருக்கி

குணம்:

”வாந்திபித்த தோடமொடு மாறாக் கடுப்பனலஞ்

சேர்ந்துனின்ற மூலரத்தந்த் தீர்க்குங்காண்- மாந்த்தளிர்க்கை

மாதே-யிரத்தபுஷ்டி வல்லபலன் உண்டாகும்

பூதலத்துள் மாதுலையின் பூ”

இதனால் குருதிவாந்தி, வயிற்றுக்கடுப்பு, வெப்பம், குருதுமூலம் இவை போகும்.

இது குருதியைப் பெருக்கும்.வன்மையை தரும்.

பிஞ்சு:

”மலக்கழிச்சல் சீதத்தால் வந்த கழிச்சல்
சலக்கழிச்சல் சோறியாற் சாரும்- பலக்கழிச்சல்
மாளும் புளிப்பான மாதுளம் பிஞ்சையுண்ண
ஆளும்கண் மாதே அறி”

இதனால் கழிச்சல் வகைகள் யாவும் தீரும்.

பயன்கள்:

பூவை உலர்த்தி சூரணித்து அதில் வேலம்பிசின் தூள் 4கிராம் சேர்த்து வேளைக்கு 260-390 வீதம் கொடுத்து வர சீதக்கழிச்சல், குருதிக்கழிச்சல் தீரும்.

பிஞ்சை குடி நீரிட்டு பேதி, அதிசாரம் முதலியவைகளுக்கு கொடுக்கலாம்.

மாதுளங் குடிநீரினால் சுரக்காய்ச்சல் தீரும்.(தேரன் 100)

Chemical constituents:

Sitosterol and ursolic acid isolated .Two tannins-punicalagin and punicalin isolated from isolated from peels and their structures determined, hydrolysis of punicalagin yielded ellagic acid and punicalin, the latter yielded glucose and a tetralactone.Pectin isolated from fruits contained mannose,

galactose, rhamnose, arabinose, and glucose.The principal sugar acid is Galacturonic acid.

Apigenin glucoside, Betulinic acid, callistephin, Chrysanthamin, Gallic acid, Pelliterine and its derivative, Piperidine and its derivative, polyphenols, sedridine, estradiol.

Properties and Uses:

- The root bark as well as stem bark of the plant are astringent and anthelmintic specifically against the tape worms.
- The fresh pomegranate juice is used as an ingredient of cooling(refrigerant) and for dyspepsia.The rind is valued as an astringent in diarrhea and dysentery.
- The juice of the leaves and young fruit and also the decoction of the bark are used in dysentery
- The dried flowers (Gulnar) are used in haematuria, haemorrhoids, haemoptisis, and dysentery.
- The powdered flowerbuds are also used in bronchitis.
- A decoction of the seed is used to treat syphilis.
- Juice of the fruit is used to treat jaundice and diarrhea.
- The fruit pulp and the seed are a stomachic.
- The root and the stem bark have astringent and anthelmentic properties.

Toxicological study:

The aquous extract of Punica granatum fruit skin in a daily dose of 0.4ml was found to be highly toxic leading to mortality in all the male house

sparrows(Passer domesticus) in 72 hours.The female sparrow showed less mortality(2 out of 6).The exact appeared to be neurotoxic.(Singh &Lal 1980)

Pharmacological Activity:

Anti microbial activity, Anti oxidant, Anthelmentic, Anti diarrhoeal, Anti ulcer, Anti bacterial, Anti inflammatory, Anti convulsant, Thrombolytic.

5.சாதிக்காய்: ***Myristica fragrans***

பயன்படும் உறுப்பு: காய்

சுவை: துவர்ப்பு, கார்ப்பு; தன்மை-வெப்பம்; பிரிவு-கார்ப்பு

செய்கை:

வெப்பமுண்டாக்கி

அகட்டுவாயகற்றி

மூர்ச்சையுண்டாக்கி

மணமூட்டி

காமப்பெருக்கி

உரமாக்கி

குணம்:

'தாது நட்டம் பேதி சருவாசி யஞ்சிர நோய்

ஓதுசுவா சங்காசம் உட்கிரணி - வேதோ

டிலக்காய் வரும்பிணிபோம் ஏற்றமயல் பித்தங்

குலக்கா யருந்துவர்க்குக் கூறு'

இதனால் விந்து குறைவு, பெருங்கழிச்சல், வாயுவினாலுண்டாகும் நோய், தலைவலி, இரைப்பு(சுவாசம்), இருமல்(காசம்), நாட்பட்ட கழிச்சல், வெப்பத்தை முன்னிட்டு வரும், பிணிகள் ஆகியவை போகும்.

மேலும் இது வயிற்று வலி, வயிற்றுப்பொருமல், அக்கினி மந்தம் இவைகளையும் போக்கும்.

பயன்கள்:

2 கிராம் தூளைப் பாலிற் கலக்கி பெருங்கழிச்சலுக்கு கொடுக்கலாம்.

சாதிக்காய் ஊறல் குடிநீர் வாந்தி பேதியிலுண்டாகும் நீர்வேட்கைக்கு கொடுக்கலாம்.

Chemical constituents:

Major constituents of nutmeg oil and d-b-pinene, Myristicin, Linalool, safrol, dl-a-pinene, and Linalyl acetate.

Uses:

Nutmeg oil is used to flaour liquers, canned soups, and other food products.

Solvent extracted oleoresin as such and in encapsulated form is used as substitute for the whole or ground spice.

Pharmacological Activity:

Antibacterial activity,Antimicrobial activity, Antifungal activity, Anti convulsant, Anti depressant activity.

Materials And Methods

4. MATERIALS AND METHODS

Kanakazhichal is one of the common illnesses in children. In our NIS OPD, a number of cases are approaching Kuzhandhai maruthuvam department daily with the Symptomps of KanaKazhichal.Hence i was proposed to study about the disease. A Protocol was prepared and submitted before IEC of National Institute of Siddha. The IEC approval number is IEC of NIS, approval No:NIS/IEC/8-14/22-26-08-2014.The trial registred in Clinical trial Registry of India with Reg .No.CTRI/2016/04/006787. After obtaining approval from the committee, the clinical study on Kanakazhichal(Bacillary Dysentery)in children and the drug of choice Adhimadhura Maathirai was carriedout asper the protocol.

The required drugs were purchased from a raw drug shop and authenticated by the medicinal bota nist. The medicine was prepared in Gunapadam lab of National institute of Siddha after proper purification as per classical siddha literature . The prepared medicine was also authenticated by the concerned Head of the Dept of Gunapadam for its completeness.

Even though the ingredients of the trial drugs is a purely herbal combination, the scientific validation of the study drug ADHIMADHURA MAATHIRAI was done through physic chemical and antibacterial activity .

PREPARATION OF THE TRIAL DRUG:

ADHIMADHURA MAATHIRAI:

Adhimadhuram (*Glycerrhiza glabra*)

Adhividayam (*Aconitum heterophyllum*)

Saathikkai (*Myristica fragrans*)

Maathulam poo (*Punica granatum*)

Seeragam (*Cuminum cyminum*)

Maathulam saaru (or) puliaarai saaru

Above given rawdrugs are taken in equal amount

PURIFICATION:

Adhividayam: Remove the nodes and dry it in the shade

Saathikkai: Remove the nodes and dry it in the shade

Adhimadhuram: Wash it in plain water and remove the outer skin and cut it into pieces latter dry it in shade

Seeragam: Remove the dust and dry it well .

PREPARATION:

The above purified drugs are finely powdered and grounded with maadhulai juice (or) puliarai juice and make into pills (Thudulangai alavu) and dried in shade

DURATION:

Adhimadhura Maathirai b.d with hot water in (thudhulangai alavu) 580mg for 3 days

After finishing the Drug preparation and preclinical studies, 40 cases were selected from the OPD & IPD of Kuzhandhai Maruthuvam Department,Ayothidoss Pandithar Hospital, National Institute of Siddha. They were treated with the trial drug ADHIMADHURA MAATHIRAI and observed for prognosis clinically.

FIG-1 Glyzyrrhiza glabra

(Adhimadhuram)

FIG-2 Cuminum cyminum

(Seeragam)

FIG-3 Aconitum heterophyllum

(Athividayam)

FIG-4 Myristica fragrans

(Saathikkai)

FIG-5 Punica granatum (Flower)

(Maathulam poo)

FIG-6 Punica granatum(Fruit)

(Maadhulai)

Adhimadhura Maathirai

4.1 PRECLINICAL STUDIES:

A.PHYSIOCHEMICAL ANALYSIS OF ADHIMADHURA MAATHIRAI:

The Physiochemical analysis of the drug ADHIMADHURA MAATHIRAI was done at Siddha Central Research Institute (SCRI), Arumbakkam Chennai. Since the physical form of the drug is in Mathirai(pills) the parameters such as Loss of drying at 105C, Total ash, Acid insoluble ash, Water insoluble ash, Alcohol insoluble ash, Disintegration time, Reducing sugar, Total sugar was done as recommended by "Protocol for testing of ASU medicine,PLIM,Ghaziabad.

1.Loss on drying

Loss on dying is the loss of mass expressed as percent w/w. About 10g of drug sample was accurately weighed in a dried and tared flat weighing bottle and dried at 105C for 5hrs. Percentage was calculated with reference to initial weight.

2.Total Ash

Take about 2 or 3 g, accurately weighed, of the ground drug in a tarred platinum or silica dish previously ignited and weighed. Scatter the ground drug in a fine even layer on the bottom of the dish. Incarnated by gradually increasing the heat-not exceeding dull red heat- until free from carbon, cool and weigh.

If a carbon free ash cannot be obtained in this way, exhaust the charred mass with hot water, collect the residue on an ash less filter paper, increate the residue and filter paper, add the filtrate, evaporate to dryness and ignite at low temperature. Calculate the percentage of ash with reference to the air dried drug.

3.Acid insoluble Ash

Boil the total ash with for five minutes with 25 ml of dilute hydrochloric acid, collect the insoluble matter in a Gooch crucible or on an ash less filter paper, wash with hot water, ignite, and weigh. Calculate the percentage of acid- insoluble ash with reference to the air dried drug.

4.Water Soluble Extractive

1gm of air dried drug, coarsely powered was macerated with 100ml of distilled water in a closed flask for twenty four hours shaking frequently. Solution was filtered and 25 ml of filtrated was evaporated in a tarred flat bottom shallow dish, further dried at 1000 C and weighted .The percentage of water soluble extractive was calculated with reference to the air dried drugs

5.Alcohol Soluble Extractive

1 gm. of air dried drugs, coarsely powdered was macerated with 100 ml. alcohol in closed flask for 24 hrs. With frequent shaking. It was filtered rapidly taking precaution against loss of alcohol. 25ml of filtrate was then evaporated in a tarred flat bottom shallow dish, dried at 1000C and weighted. The percentage of alcohol soluble extractive was calculated with reference to air dried drug.

6.pH

The pH of the formulations in 1% w/v and 10% w/v of water soluble portions was determined using simple glass electrode pH meter.

7.Disintegration time:

The time required for a tablet to break up into granules of specified size under carefully specified test condition. The conditions of the laboratory test, in vitro are set to stimulate those which obtained in vivo. Factors such as the kind and amount of tablet binders and the degree of compression used in compacting the tablet ingredients help determine disintegration time.

8.Reducing sugar test:

Benedict's reagent is an aqueous solution of copper(II)sulphate, sodium carbonate and sodium citrate. To approximately 2 cm of test solution add an equal quantity of Benedict's reagent. Shake and heat for a few minutes at 95C in a water bath. A precipitate indicates reducing sugar.

B.CHEMICAL ANALYSIS OF ADHIMADHURA MAATHIRAI

Chemical Analysis of Adhimadhura Mathirai was done at the Biochemistry lab at National Institute of Siddha, Chennai by the method of Kolkate.

Preparation of Extract:

5gm of sample was taken in a 250ml clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is

cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water. This preparation is used for the qualitative analysis of acidic/basic radicals and chemical constituents in it.

The chemical analysis of ADHIMADHURA MAATHIRAI

S.No	EXPERIMENT	OBSERVATION	INFERENCE
1.	Physical Appearance of extract	Yellow in colour	
2.	**Test for Silicate** a. A 2ml of the sample was shaken well with distilled water.	Sparingly soluble	Absence of Silicate
3.	**Action of Heat:** A 2ml of the sample was taken in a dry test tube and heated gently at first	No White fumes evolved. No brown fumes	Absence of Carbonate
4.	**Flame Test:** A 2ml of the sample was made into a paste with con. HCl in a watch glass and introduced into non-luminous part	No bluish green flame	Absence of copper
5.	**Ash Test:** A filter paper was soaked into a mixture of extract and dil. cobalt nitrate solution and introduced into the	Appearance of yellow colour flame	Absence of sodium

Preparation of Extract:

5gm of sample was taken in a 250ml clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water. This preparation is used for the qualitative analysis of acidic/basic radicals and biochemical constituents in it.

S.N	EXPERIMENT	OBSERVATION	INFERENCE
	I. Test For Acid Radicals		
1.	**Test For Sulphate:** a.2ml of the above prepared extract was taken in a test tube to this added 2ml of 4% dil ammonium oxalate solution	No Cloudy appearance present.	Absence of sulphate.
2.	**Test For Chloride:** 2ml of the above prepared extracts was added with 2ml of dil,HCl is added until the effervescence ceases off..	No Cloudy appearance present.	**Absent of Chloride**
3.	**Test For Phosphate:** 2ml of the extract were treated with 2ml of dil.ammoniummolybdate	No Cloudy yellow appearance	**Absent of Phosphate**

	solution and 2ml of con.HNo3	present	
4.	**Test For Carbonate:** 2ml of the extract was treated with 2mldil. magnesium sulphate solution	No cloudy appearance.	Absence of carbonate
C	**Test For Nitrate:** 1gm of the extract was heated with copper turning and concentrated H_2So_4 and viewed the test tube vertically down.	No Brown gas is evolved	Absence of nitrate
6.	**Test For Sulphide:** 1gm of the extract was treated with 2ml of con. HCL	No rotten egg smelling gas is evolved	Absence of sulphide
7.	**Test For Fluoride & Oxalate:** 2ml of extract was added with 2ml of dil. Acetic acid and 2ml dil.calcium chloride solution and heated**.**	No cloudy appearance.	Absence of fluoride and oxalate
	Test For Nitrite:	No	Absence of nitrite

8.	3drops of the extract was placed on a filter paper, on that-2 drops of dil.acetic acid and 2 drops of dil.Benzidine solution is placed.	characteristic changes	
9.	**Test For Borate:** 2 Pinches (50mg) of the extract was made into paste by using dil.sulphuric acid and alcohol (95%) and introduced into the blue flame	Appearance of bluish green colour	Absence of borate

Results of Acid radicals studies

S.no	**Parameter**	**Observation**	**Result**
1	Test for Sulphate	No Cloudy appearance Present	Negative
2	Test for Chloride	No Cloudy appearance present	Negative
3	Test For Phosphate	No Cloudy yellow appearance present	Negative
4	Test For Carbonate	-	Negative
5	Test For Nitrate	-	Negative

6	Test for Sulphide	-	Negative
7	Test For Fluoride &oxalate	-	Negative
8	Test For Nitrite	-	Negative
9	Test For Borax	-	Negative

Interpretation

The acidic radicals test shows no acid radicals seen.

III. Miscellaneous			
1.	**Test For Starch:** 2ml of extract was treated with weak	No Blue colour developed	Absence of starch
2.	**Test For Reducing Sugar:** 5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and	Brick red colour is developed	Presence of reducing sugar

3.	**Test For The Alkaloids**: a) 2ml of the extract was treated with 2ml of dil.potassium Iodide solution. b) 2ml of the extract was treated with 2ml of dil.picric acid. c) 2ml of the extract was treated with 2ml of dil.phosphotungstic acid.	Yellow colour developed	**Presence of Alkaloid**
4.	**Test For Tannic Acid:** 2ml of extract was treated with 2ml of dil.ferric chloride solution	Blue-black precipitate is obtained	Presence of Tannic acid
5.	**Test For Unsaturated Compound:** To the 2ml of extract 2ml of dil.Potassium permanganate solution is added.	Potassium permanganate is not decolourised	Absence of unsaturated compound
6.	**Test For Amino Acid:** 2 drops of the extract was placed on a filter paper and dried well. 20ml of Burette reagent is added**.**	No violet colour	Absence of amino acid
7	**Test For Type Of Compound:**	green and red colour	Presence of quinol, epinephrine

.	2ml of the extract was treated with 2 ml of dil.ferric chloride solution.	Present No Violet colour developed No Blue colour developed.	pyrocatechoantipyrine Aliphatic amino acid and meconic acid. Apomorphine salicylate and Resorcinol are absent Morphine, Phenol cresol and hydrouinone are present.

C.ANTIBACTERIAL ACTIVITY OF ADHIMADHURA MAATHIRAI

The aqueous extract of the trial drug Adhimadhura Maathirai was used for antibacterial study (ozkan *et al*., 2004; Janarthanam and Sumathi, 2010). Different concentration (10, 20 and 30 mg/ml) of the concentrated aqueous of trial drug Adhimadhura Maathirai was tested for its antimicrobial strain such as *Bacillus cereus, Streptococcus pyogenes, Staphylococcus aureus, Pseudomonas aeruginosa and Escherichia coli.* The bacterial cultures were grown in Mueller Hinton Agar and Mueller Hinton broth (Himedia) (Lopez *et al*., 2001).

Antibacterial activity was measured using the standard method of diffusion disc plates on agar (Erturk *et al*., 2003). Then 0.1ml of each culture of bacteria was spread on agar plate surfaces. For antibacterial assay, all bacterial strains were grown in Mueller Hinton Broth Medium (Hi media) for 24 hours at 37°C and plated on

Mueller Hinton Agar (Hi media) for agar diffusion experiments. Paper disc (6mm in diameter) were placed on the agar medium to load 20µl of different concentrations of aqueous extract of the trial drug Adhimadhura Maathirai were tested. Inhibition diameters were measured after incubation for 24 - 48 hours at 37°C.

4.2 CLINICAL STUDIES:

Population and Sample:

Population consist of all patients with Kanakazhichal (Bacillary dysentery)satisfying the inclusion and exclusion criteria mentioned below .The sample consists of patients attending the OPD/IPD of the Ayothidoss Pandithar Hospital of the National Institute of Siddha ,Chennai-47

Sample size:

The trial size was 40 patients

Inclusion Criteria:

- Age between 5-12 years
- Icreased frequency of stool with mucus or mucus with blood atleast 3-4 times per day
- Rumbling noise in the intestine
- Fever
- Tenesmus
- Patients with history of abdominal cramps
- Patient/Guardian of the patient willing to sign the informed consent.

Exclusion Criteria

- History of continues high-grade fever
- Signs of profuse dehydration
- History of extra intestinal complication
- History of patients with any other serious illness
- History chronic diarrhea in inflammatory bowel disease or malabsorption

Withdrawal Criteria:

- Intolerance to the drug and development of adverse reaction during drug trail
- Poor patient compliance and defaulters
- Patient turned unwilling to continue in the course of clinical trial .

STUDY ENROLLMENT

- In this study, patients reporting at the NIS OPD with five or more clinical symptoms like mucous in the stools or blood with mucous in stools, fever, tenesmus, abdominal cramps, and malaise were examined clinically for enrolling in this study based on the inclusion and exclusion criteria.
- The patients who enrolled were informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them.
- After ascertaining the patients' willingness, informed consent (Form II) was obtained in writing from their parents in the consent form.

- All these patients was given investigator phone number to report easily if any study related problems arise.
- Complete clinical history, complaints and duration, examination findings and other relavent history were recorded in the prescribed Case sheet proforma history and clinical assessment forms separately. Screening Form(form- I)was filled up. Form III, Form–IV and Form –V were used for recording the patient's history, clinical examination of symptoms and signs and laboratory investigations respectively.
- Patient was advised to take the trial drug and appropriate dietary advice was given according to the patients' perfect understanding

CONDUCT OF THE STUDY:

The trial drug "Adhimadhura Maathirai" was given for 3 days. For OP patients before and after treatment the clinical assessment was done and prognosis is noted. For IP patients the drug was provided daily and prognosis were noted and clinical assessment will be done. Laboratory investigations were done 1st day of the trial. After the end of the treatment, the patient was advised to visit the OPD for another 1 months for follow-up.

DATA COLLECTION FORMS

FORM I – SCREENING & SELECTION PROFORMA

FORM II – CONSENT FORM

FORM III – CASE REPORT FORM

FORM IV – PATIENT'S INFORMATION SHEET

FORM V – WITHDRAWAL FORM

FORM VI – PHARMACOVIGILANCE FORM

FORM VII – ASSENT FORM

FORM VIII – ADVERSE REACTION

DATA MANAGEMENT

- After enrolling the patient in the study, a separate file for each patient was opened and all forms were filed in the file. Study No. and Patient No. were entered on the top of file for easy identification. Whenever study patient visits OPD during the study period, the respective patient file was taken and necessary recordings were made at the assessment form or other suitable form.
- The screening forms were filed separately.
- The Data recordings in all forms were monitored and scrutinized by HOD, Dept of Kuzhanthai Maruthuvam .
- Data analysis was done with the help of Senior research officer (statistics) of NIS
- The experimental drug may have good efficacy and safety in clinical study.

ADVERSE EFFECT / SERIOUS EFFECT MANAGEMENT:

If the trial patient develops any adverse reaction, he/she would be immediately withdrawn from the trial and proper management will be given in OPD of National Institute of Siddha. The details of adverse reactions will be recorded in prescribed

Pharmacovigilance form and the same will be reported to Regional Pharmacovigilance centre.

ETHICAL ISSUES:

1. To prevent any infection, proper sterilized lab equipments was used.
2. No other external or internal medicines was used.
3. The data collected from the patient was kept confidentially. The patient was informed about the diagnosis, treatment and follow-up.
4. After the consent of the patient (through consent form) they was enrolled in the study.
5. Informed consent was obtained from the patient explaining in the understandable language to the patient.
6. Treatment were provided free of cost.
7. In conditions of treatment failure, adverse reactions, patients was given alternative treatment at the National Institute of Siddha with full care throughout the end.

TESTS AND ASSESSMENTS :

a)Siddha assessments :

Poriyalarithal , pulanalarithal , mukkutra nilai , ezhu udal thathukkal , envagai thervugal , neerkuri, neikuri etc.

b)Clinical assessments:

Increased frequency of stool with mucus or mucus with blood , fever , Abdominal pain,Tenesmus, Rumbling in the intestine

c)Lab investigation :

Blood routine –TC, HB, DC

Stool culture

d)Siddha investigation:

Neerkuri , Neikuri

40 Patients with confirmed diagnosis of *ADIMADHURA MAATHIRAI* with satisfying the inclusion criteria were enrolled after obtaining written informed consent and were to receive *KANAKAZHICHAL (Bacillary dysentery)* with dosage of 1tablet (580mg) BID for 3 day.

Results And Observations

5.RESULTS AND OBSERVATION:

5.1 PRECLINICAL STUDY:

A. PHYSICOCHEMICAL ANALYSIS OF ADHIMADHURA MAATHIRAI

S.No.	Parameters	Results
1	Loss of Drying at 105C	12.80%
2	Total ash	4.88%
3	Acid soluble ash	0.73%
4	Water soluble Extractive	7.15%
5	Alcohol soluble Extractive	6.99%
6	pH	4.40
7	Disintegration Test	29 min
8	Average weight of 20 tablets	0.3015 g
9	Reducing sugar	4.41%
10	Total sugar	14.75%

Loss of drying indicates the moisture content. The total ash substance is the measure of inorganic constituents present in the drug.High ash contents explains its unsuitable nature to be used as drug.This formulation statisfy the pharmacopoeial standards and as per the WHO Guidelines.

B. CHEMICAL ANALYSIS OF ADHIMADHURA MAATHIRAI

I. Test For Basic Radicals			
1	**Test For Lead:** 2ml of the extract was added with 2ml of dil.potassium iodine solution.	No Yellow precipitate is obtained	Absence of lead
2.	**Test For Copper:** **a.** One pinch (25mg) of extract was made into paste with con. HClin a watch glass and introduced into the non-luminuous part of the flame.	No blue colour precipitate	Absence of copper
3.	**Test For Aluminium:** To the 2ml of extract dil.sodium hydroxide was added in 5 drops to excess.	Shows Brown colour precipitate	Presence of Aluminium.
4.	**Test For Iron:** a. To the 2ml of extract add 2ml of dil.ammonium solution	No Red colour appeared	Absence of Iron
5.	**Test For Zinc:** To 2ml of the extract dil.sodium hydroxide solution was added in 5 drops to excess and dil.ammonium chloride is added.	NoWhite precipitate is formed	Absence of Zinc
6.	**Test For Calcium:** 2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution	No Cloudy appearance and white precipitate	Absent of calcium

7.	**Test For Magnesium:** To 2ml of extract dil.sodium hydroxide solution was added in drops to excess.	No White precipitate is obtained	Absent of magnesium
8.	**Test For Ammonium:** To 2ml of extract 1 ml of Nessler's reagent and excess of dil.sodium hydroxide solution are added.	Mild Brown colour appeared	Presence of ammonium
9.	**Test For Potassium:** A pinch (25mg) of extract was treated of with 2ml of dil.sodium nitrite solution and then treated with 2ml of dil.cobalt nitrate in 30% dil.glacial acetic acid.	No Yellow precipitate is obtained	Absence of potassium
10.	**Test For Sodium**: 2 pinches (50mg) of the extract is made into paste by using HCl and introduced into the blue flame of Bunsen burner.	No yellow colour flame evolved.	Absence of sodium
11.	**Test For Mercury**: 2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.	No Yellow precipitate is obtained	Absence of Mercury
12.	**Test For Arsenic:** 2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.	No Brownish red precipitate is obtained	Absence of arsenic

Results of basic radicals studies:

S.NO	Parameter	Observation	Result
1	Test for Lead	-	Negative
2	Test for Copper	-	Negative
3	Test For Aluminium .	Brown colour present	Positive
4	Test For Iron .	-	Negative
5	Test For Zinc	-	Negative
6	Test for Calcium	-	Negative
7	Test For Magnesium	-	Negative
8	Test For Ammonium	Mild brown colour appears.	Positive
9	Test For Potassium	-	Negative
10	Test For Sodium	-	Negative
11	Test For Mercury	-	Negative
12	Test For Arsenic	-	- Negative

Interpretation

The basic radical test shows the presence of **Aluminium &Ammonium,** and absence of heavy metals such as lead, Iron, arsenic and mercury.

Miscellaneous:

S.NO	Parameter	Observation	Result
1	Test for Starch	-	Negative
2	Test for Reducing sugars	-	Negative
3	Test For Alkaloids .	Yellow colour developed	Positive
4	Test For Tannic acid .	Blue-black precipitate obtained	Positive

5	Test for unsaturated compounds	-	Negative
6	Test for Amino acid	-	Negative
7	Test For Type of compounds	Green and Red colour present	Positive

Interpretation

The Miscellaneous test shows the presence of **Alkaloid, Tannic acid, Type of Compounds.**

C. ANTIBACTERIAL STUDY OF ADHIMADHURA MAATHIRAI

The aqueous extract of the trial drug ADHIMADHURA MAATHIRAI was used f**or ant**ibacterial study in different concentration (10, 20, 30mg/ml)

Microorganisms Tested	**Concentrations of aqueous extract (mg/ml) Zone of Inhibition (mm)**		
Aqueous Adhimadhura Maathirai Extract	**10mg/ml**	**20mg/ml**	**30mg/ml**
Bacillus cereus	**-**	**-**	**13**
Streptococcus pyogenes	**-**	**-**	**10**
Pseudomonas aeruginosa	**-**	**-**	**9**
Staphylococcus aureus	**-**	**-**	**10**
Escherichia coli	**-**	**-**	**9**

Interpretation:

The antibacterial study of the trial drug shows Bacillus cereus had large zone of inhibition in30mg/ml of extract.steptococcus pyogens ,E.coli, staphylococcus aureus had mild zone of inhibition than the above.

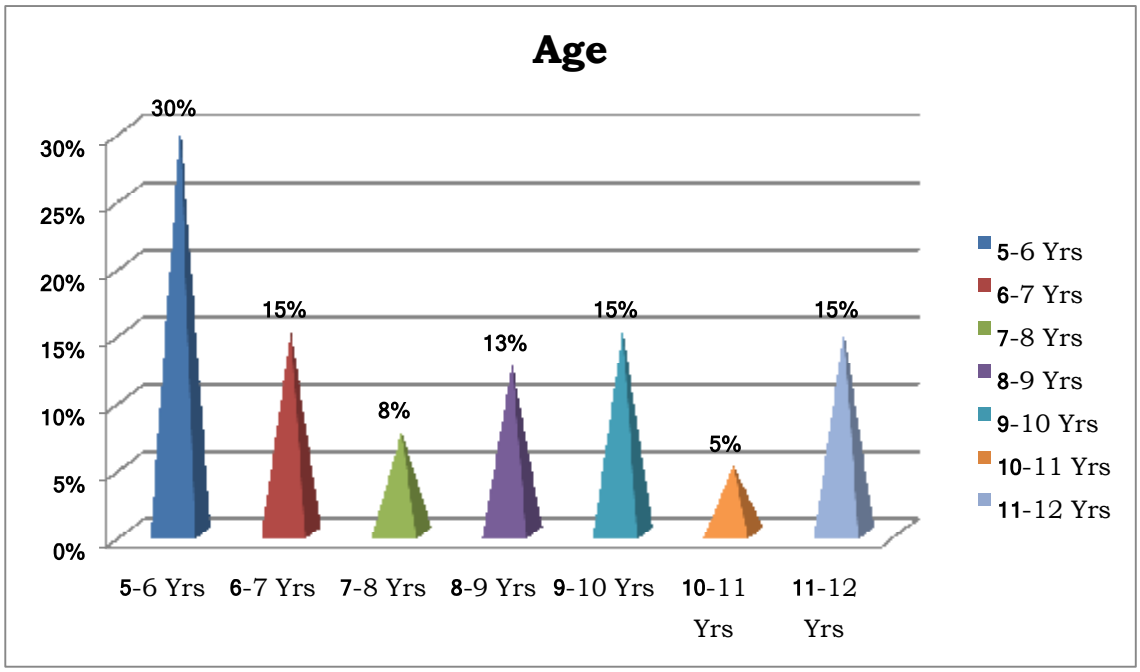
5.2 CLINICAL STUDIES

Results were observed with respect to the following criteria:

1. Age
2. Sex
3. Socio Economic Status
4. Religion
5. Diet
6. Nilam
7. Paruvakaalam
8. Uyir thathukkal
9. Ezhu udal kattugal
10. Envagaithervugal
11. Neikuri
12. Duration of Illness
13. Clinical features

Table1. Distributions of patients with Kanakazhichal according to Age

S.No	Age	Percentage	No of cases / 40
1	5-6 Yrs	30%	12
2	6-7 Yrs	15%	6
3	7-8 Yrs	8%	3
4	8-9 Yrs	13%	5
5	9-10 Yrs	15%	6
6	10-11 Yrs	5%	2
7	11-12 Yrs	15%	6

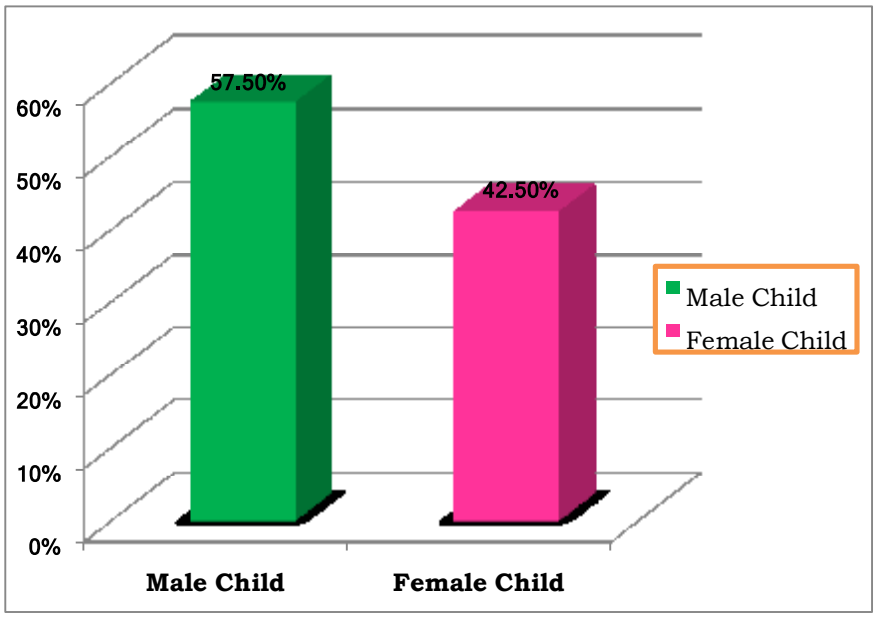


Inference:

Out of 40 patients, 30 % of cases were 5-6years, 15 % were 6-7 years, 8 % were 7-8 years, 13 % were 8-9 years, 15 % were 9-10 years, 5 % were 10-11 years and 15 % were 11-12 years **(Table1).**

Table2. Distributions of patients with Kanakazhichal according to Gender

S. No	Sex	Percentage	No of cases / 40
1	Male Child	57.50%	23
2	Female Child	42.50%	17



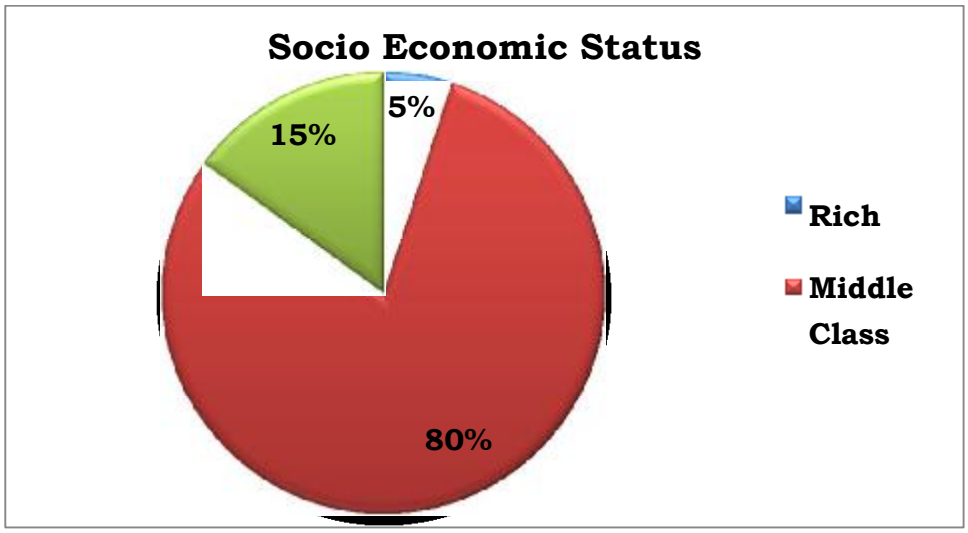
Inference:

Out of 40 patients 57.50% were male children and 42.50% were female children. **(Table 2)**

So there is no marked difference in sex distribution and this disease can affect either sex.

Table.3.Distribution of patients with Kanakazhichal according to socio-economic status

S. No	Socio economic Status	Percentage	No of cases / 40
1	Rich	5%	2
2	Middle Class	80%	32
3	Poor	15%	6

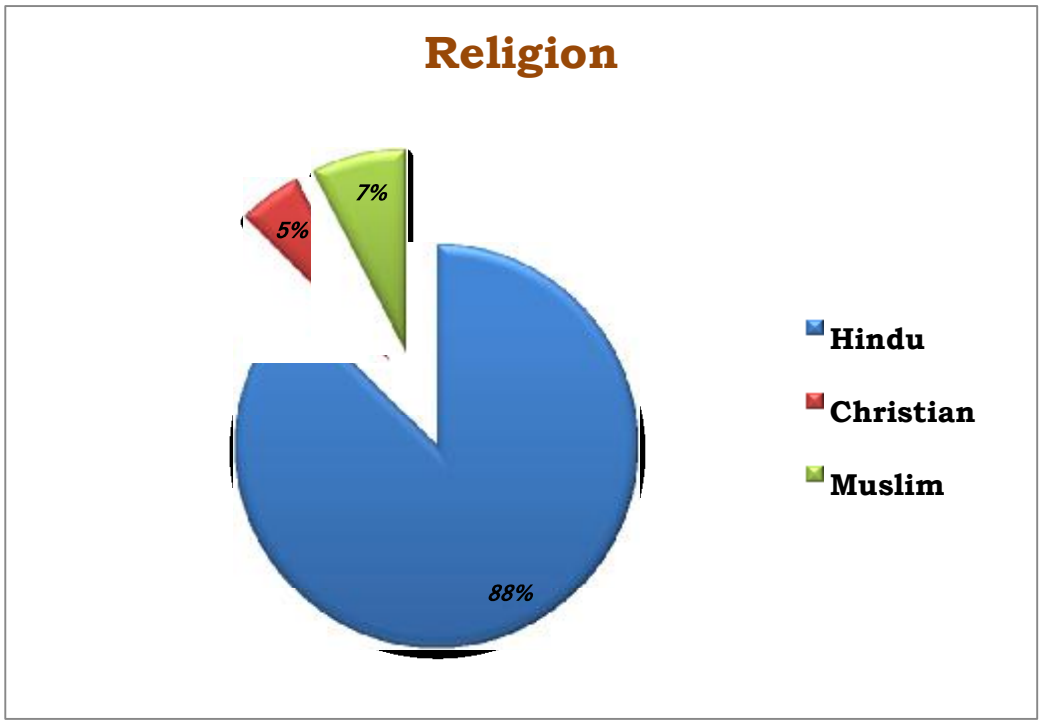


Inference:

About 15 % patients were under lower income group, 80% patients were under middle income group and 5 % patients were under high income group. The highest incidence occurred in middle income group. **(Table 3).**

Table 4.Distribution of patients with Kanakazhichal according to Religion

S. No	Religion	Percentage	No of cases / 40
1	Hindu	87.50%	35
2	Christian	5.00%	2
3	Muslim	7.50%	3

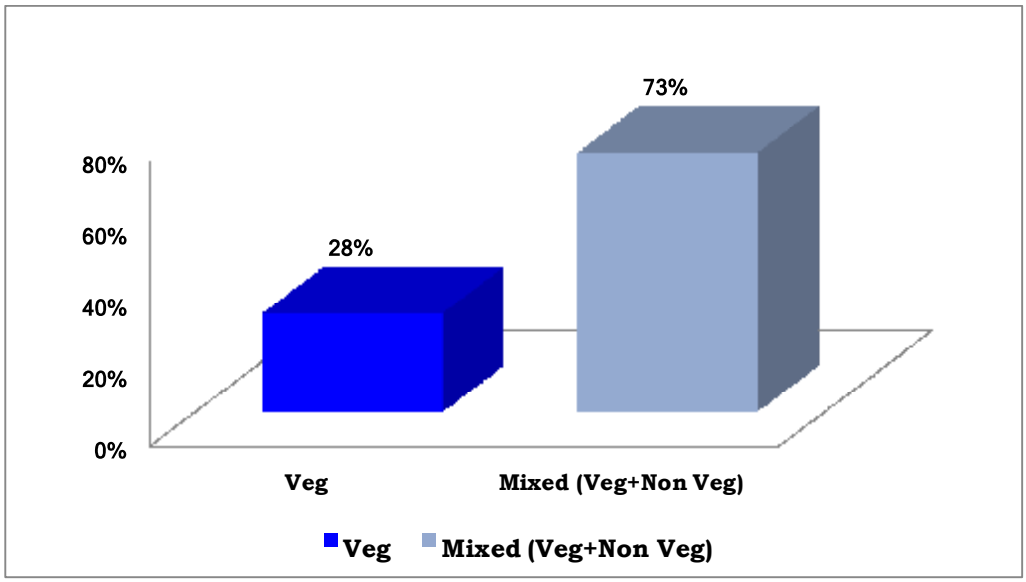


Inference

About 88 % patients were under Hindu, 7% patients were under Muslims and 5 % patients were under Christian. **(Table 4).**

Table 5.Distribution of patients with Kanakazhichal according to Diet reference

S. No	Food Habits	Percentage	No of cases / 40
1	Veg	28%	11
2	Mixed (Veg+Non Veg)	73%	29

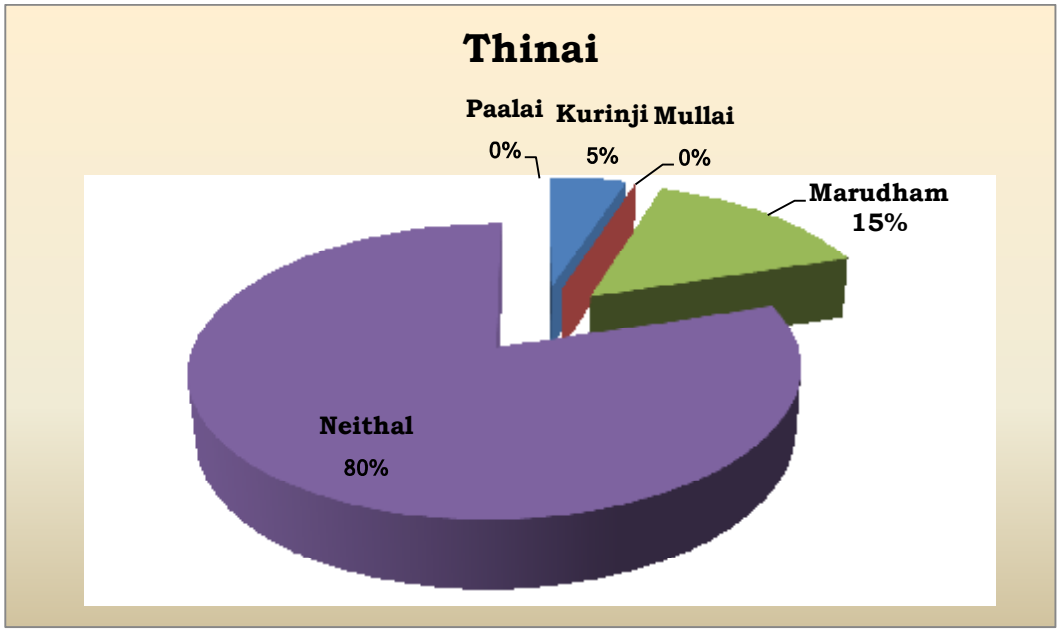


Inference:

According to diet, Vegeterian 28%, Mixed 73% were noted. **(Table 5)**

Table.6. Distribution of patients with Kanakazhi according to Nilam

S. No	Thinai (Nilam)	Percentage	No of cases / 40
1	Kurinji	5%	2
2	Mullai	0%	0
3	Marudham	15%	6
4	Neithal	80%	32
5	Paalai	0%	0

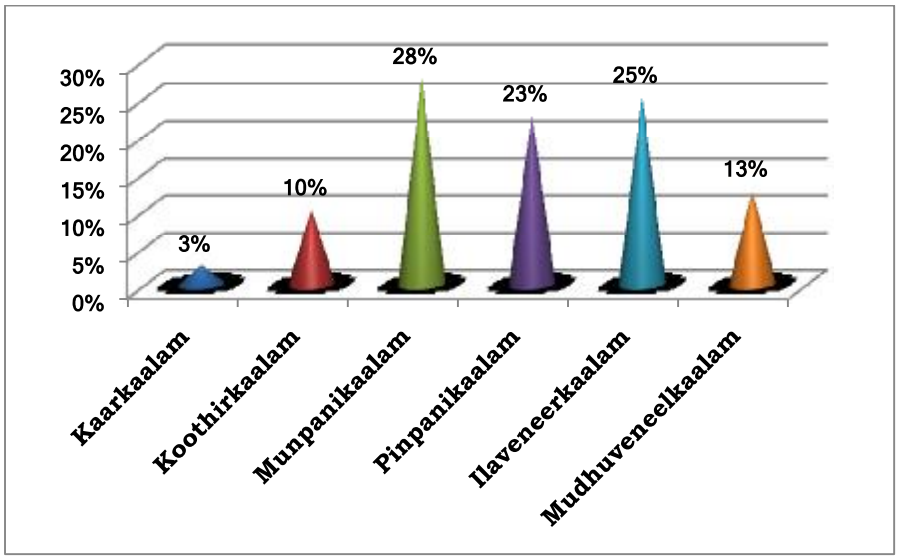


Inference:

Among 40 patients, 80 % were from Neithal land, 15 % from Marutham land, 0 % from Mullai land, 5% from Kurinji land and 0% from Paalai land**. (Table 6)**

Table.7. Distribution of patients with Kanakazhichal according to Paruvakalam

S. No	Paruva Kalam	Percentage	No of cases / 40
1	Kaarkaalam(Avani – puratasi)	3%	1
2	Koothirkaalam (Iyppasi – karthikai)	10%	4
3	Munpanikaalam(Markazhi – Thai)	28%	11
4	Pinpanikaalam(Masi – Panguni)	23%	9
5	Ilaveneerkaalam(Chitirai, Vaigasi)	25%	10
6	Mudhuveneelkaalam(Aani, Aadi)	13%	5

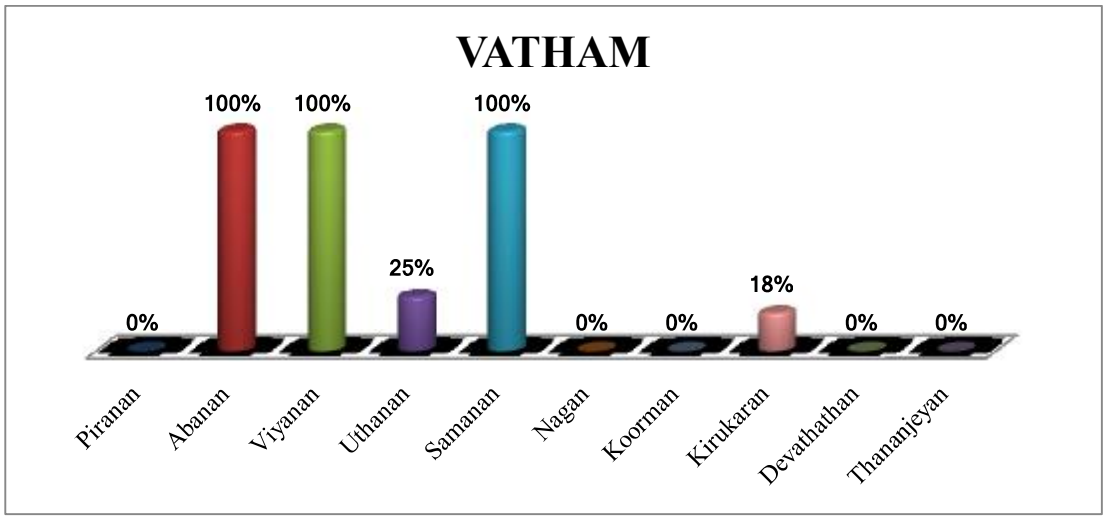


Inference:

According to paruva kaalam, high incidence of cases 28% were reported in Munpanikaalam,25% cases were reported in Ilavener kaalam 23% were reported in Pinpanikaalam, 13% cases were reported in mudhuvenel kaalam, 10% cases were reported in Koothir kaalam and 3% were from Kaar kaalam**.(Table 7)**

Table.8a. Distribution of patients with Kanakazhichal according to derangement of Vatham

S. No	Classification of Vatham	Percentage	No. of Cases
1	Piranan	0%	0
2	Abanan	100%	40
3	Viyanan	100%	40
4	Uthanan	25%	10
5	Samanan	100%	40
6	Nagan	0%	0
7	Koorman	0%	0
8	Kirukaran	18%	7
9	Devathathan	0%	0
10	Thananjeyan	0%	0

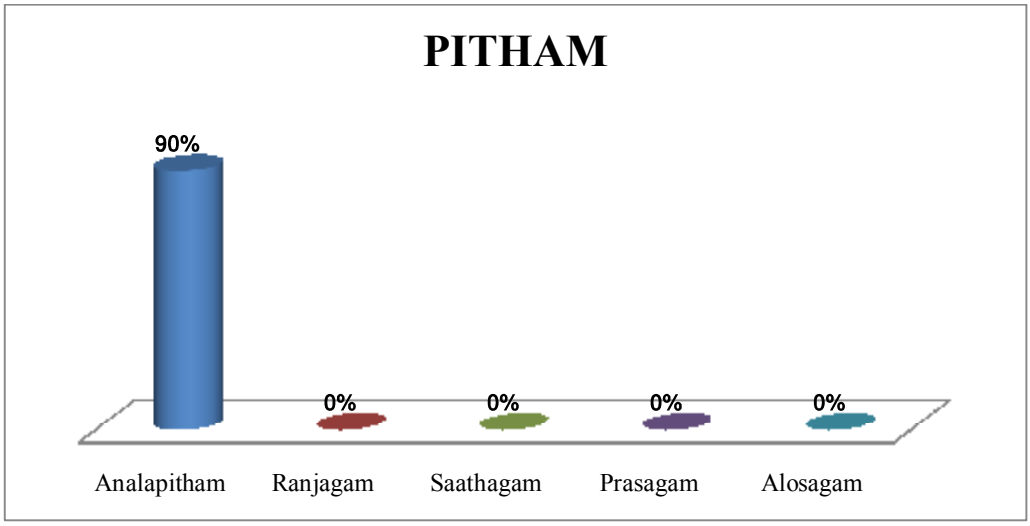


Inference:

According to Vatham, derangement of Abanan was 100%, Viyanan was 100%, Udhanan was 25%, Samaanam was affected 100 % and Kirukaran was deranged in 18% .Other types of vathas were not affected in children.**(Table-8a).**

Table.8b. Distribution of patients with Kanakazhichal according to derangement of Pitham

S. No	Types of Pitham	Percentage	No.of Cases
1	Analapitham	90%	36
2	Ranjagam	0%	0
3	Saathagam	0%	0
4	Prasagam	0%	0
5	Alosagam	0%	0

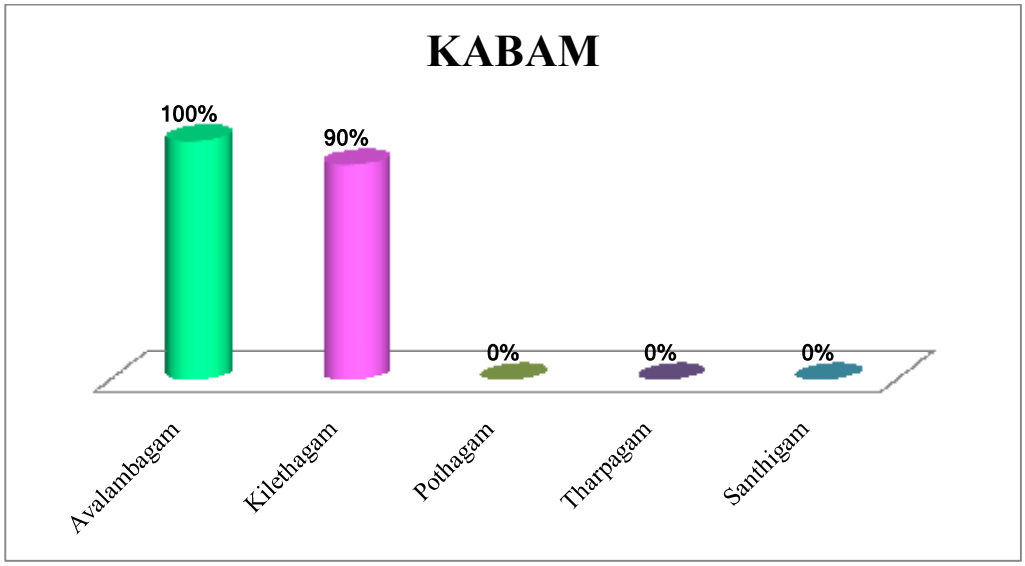


Inference:

According to Pitham, derangement of Analapitham was 90%.Other types of pitham were not affected in children with Kanakazhichal **(Table 8b).**

Table.8c.Distribution of patients with Kanakazhichal according to derangement of Kabam

S. No	Types of Kabam	Percentage	No.of Cases
1	Avalambagam	100%	40
2	Kilethagam	90%	36
3	Pothagam	0%	0
4	Tharpagam	0%	0
5	Santhigam	0%	0

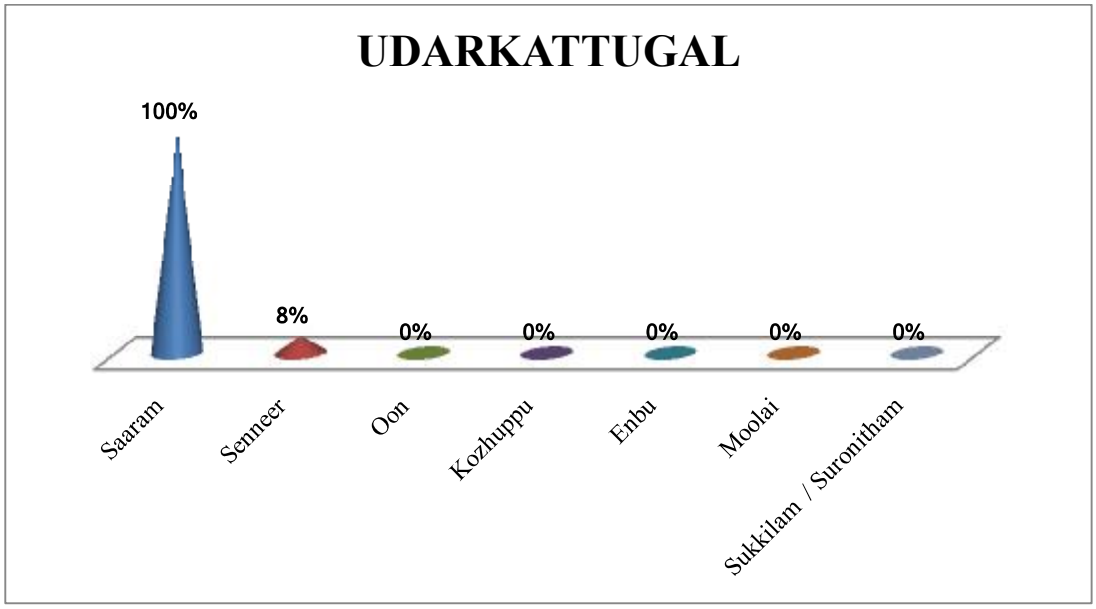


Inference:

According to Kabam, derangement of Avalambagam was deranged in 100% and Kilethagam was deranged in 90%.Other types of kabam were not affected in children **(Table.8c).**

Table.9. Distribution of patients with Kanakazhichal according to derangement of Ezhu Udarkattugal

S. No	Udarkattugal	Percentage	No.of Cases
1	Saaram	100%	40
2	Senneer	8%	3
3	Oon	0%	0
4	Kozhuppu	0%	0
5	Enbu	0%	0
6	Moolai	0%	0
7	Sukkilam / Suronitham	0%	0

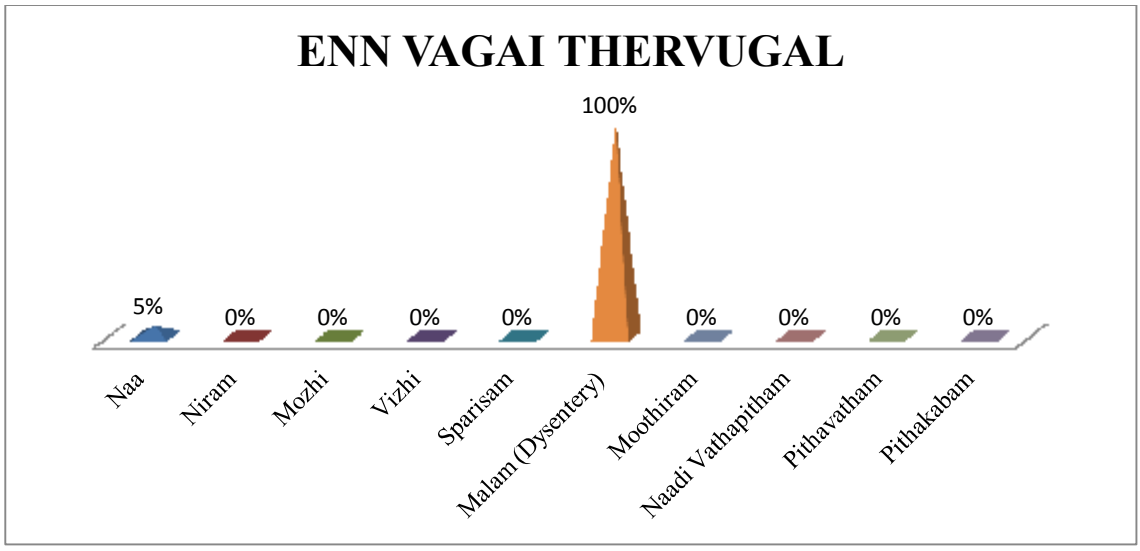


Inference:

Saaram was affected in 100% of cases and Senneer affected in 8% cases. Oon, Kozhuppu,Enbu, Moolai were not affected.**(Table 9).**

Table.10. Distribution of patients with Kanakazhichal according to derangement of Envagai thervugal

S. No	EnVagai Thervugal	Percentage	No.of Cases
1	Naa	5%	2
2	Niram	0%	0
3	Mozhi	0%	0
4	Vizhi	0%	0
5	Sparisam	0%	0
6	Malam (Dysentery)	100%	40
7	Moothiram	0%	0
8	Naadi Vathapitham	0%	0
	Pithavatham	0%	0
	Pithakabam	0%	0

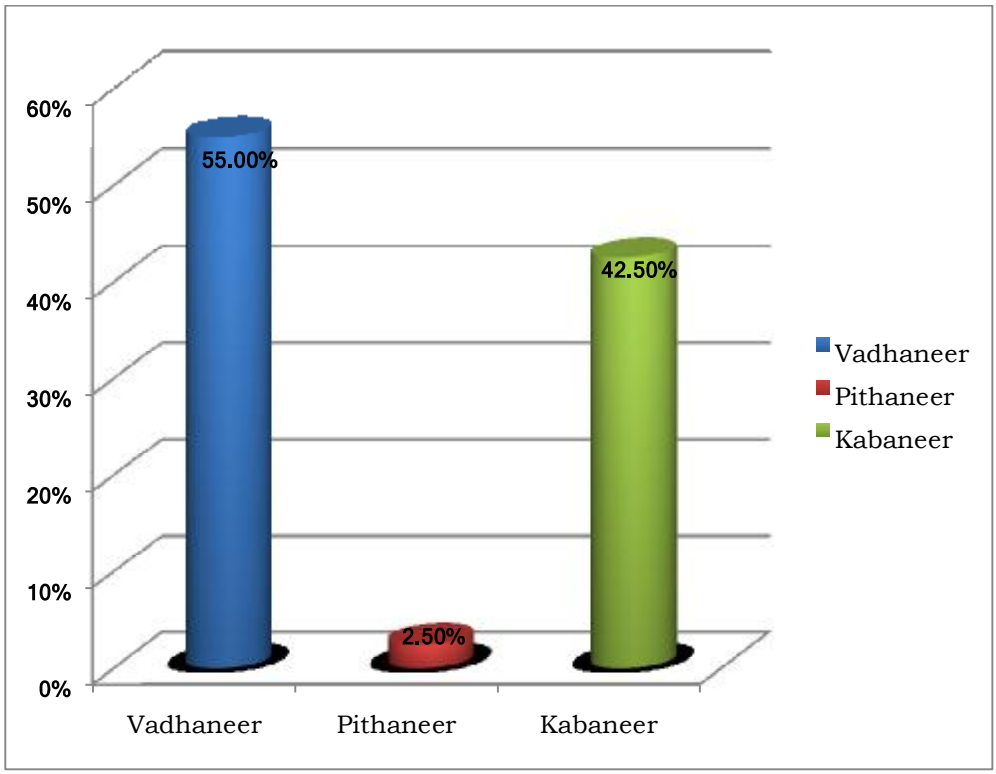


Inference:

According to Enn Vagai Thervugal, Malam (Dysentery) was observed in 100 % of cases, Naa was observed in 5% of cases. **(Table 10)**

Table.11. Distribution of patients with Kanakazhichal according to Neikuri

S. No	Neikkuri	Percentage	No of cases / 40
1	Vadhaneer	55.00%	22
2	Pithaneer	2.50%	1
3	Kabaneer	42.50%	17

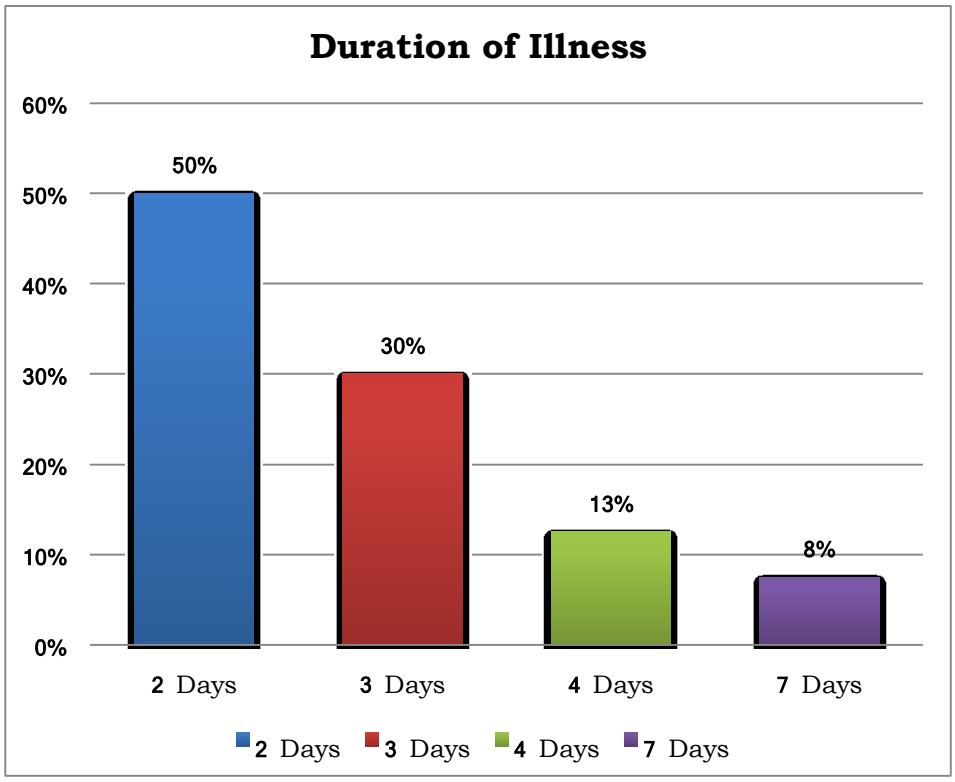


Inference

According to Neikuri, Vatha neer was observed in 55.00 % of cases,pitha neer was observed in 2.50% of cases, Kaba neer was observed in 42.50 % of cases.**(Table 11)**

Table.12. Distribution of patients with Kanakazhichal according to Duration of Illness

S. No	Duration of Illness	Percentage	No of cases / 40
1	2 Days	50%	20
2	3 Days	30%	12
3	4 Days	13%	5
4	7 Days	8%	3

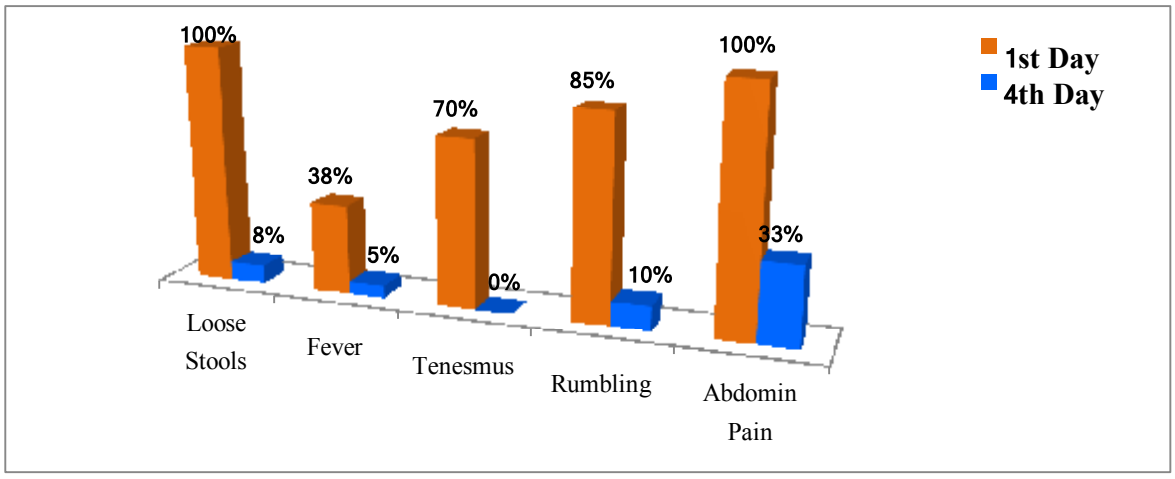


Inference

According to Duration of Illness, 50% cases were 2 days, 30% cases were 3 days, 13% cases were 4 days and 8% cases were 7 days.

(Table 13) Table.13. Distribution of patients with Kanakazhichal according to Clinical features:

S. No	Symptoms	1st Day		4th Day	
		Percentage	No.of Cases	Percentage	No.of Cases
1	Loose Stools	100%	40	8%	3
2	Fever	38%	15	5%	2
3	Tenesmus	70%	28	0%	0
4	Rumbling	85%	34	10%	4
5	Abdomin Pain	100%	40	33%	13



Inference

According to Clinical Features, 100% cases were passing loose stools in 1st day it reduced in % at the treatment of day4, 38% cases were fever before treatment when after treatment it was reduced as 5%, 70% cases were tenesmus before treatment after treatment it was reduced as 0%.4 days ,85% cases were rumbling present before treatment it was reduced as 10% in after treatment.100% of patients had abdomen pain before treatment it was reduces 33% after treatment.

STATISTICAL ANALYSIS

For clinical studies

All collected data were entered into MS Excel software using different columns as variables and rows as patients. STATA software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross- tabulations were performed. Bar diagram, Pie charts were used to describe the value of different variables for pictorial representation. The quantity variables were expressed as Mean and standard deviation and qualitative data as percentage. A probability value of less than 0.05 was considered to indicate as statistical significance.Paired 't' test was performed for determining the significance between before and after treatment.

Clinical Symptoms score before and after treatment

Treatment	Mean ± Std Dev	95% of C.I	Significance (t, p)
Before (40)	3.9 ± 2.13	3.673277	23.4
After (40)	.35± 1.7	.1382296	P <0.0001

The mean and standard deviation of KANAKAZHICHAL Before and After treatment were 3.9 ± 2.13 and 0.35 ± 1.7 respectively.Which is statistically significant P <0.0001 t-value =23.4015

The reduction of clinical symptoms after the treatment is significant (p <0.0001). The reduction in the symptoms is 91 % from the start of the treatment.

LABORATORY INVESTIGATIONS

S. No	OP/IP No	Polymorphs	Lymphocyte	Monocyts
1	G 62467	49	45	6
2	G 87627	36	58	6
3	G 90640	35	60	5
4	G 91042	55	40	5
5	F 63846	60	33	7
6	F 33179	50	43	7
7	F 10236	36	58	6
8	F 23066	84	13	3
9	G 98872	36	58	6
10	G 91964	42	53	5
11	G 91978	80	14	6
12	H 4742	55	40	5
13	G 27210	37	58	5
14	E 48510	30	65	5
15	H 14138	42	54	4
16	H 14637	35	62	3
17	F 38761	37	58	5
18	G 84276	66	30	4
19	G 49228	59	33	8
20	E 5104	41	57	2
21	H 39751	51	42	7
22	F 51934	35	62	3
23	1804	43	52	5
24	G 15162	35	62	3
25	H 43447	57	36	7
26	G 43549	48	44	8
27	G 9292	36	59	5
28	H 46418	43	54	3
29	G 89313	54	39	7
30	H 54244	59	38	3
31	H 55033	43	50	7
32	H 30254	32	64	4
33	H 19105	39	55	6
34	H 55355 / 1874	55	38	7
35	1866	39	59	2
36	H 43391	41	52	7
37	H 34051	43	50	7
38	H 68734	33	61	6
39	H 70124	40	53	7
40	1886	35	63	2

BEFORE TREATMENT

S. No	OP/IP No	Hb	T.RBC	TC
1	G 62467	10.9	4.5	6000
2	G 87627	10.4	4.7	6200
3	G 90640	9.2	4.1	6500
4	G 91042	13.2	4.8	7200
5	F 63846	11.8	5.0	5900
6	F 33179	13.6	5.0	5700
7	F 10236	10.6	5.0	6900
8	F 23066	12.6	4.5	7100
9	G 98872	12.5	4.5	5700
10	G 91964	12.5	4.5	6100
11	G 91978	13.4	5.1	5200
12	H 4742	12.2	5.2	5900
13	G 27210	11.8	4.7	5100
14	E 48510	11.8	4.1	5400
15	H 14138	10.9	4.2	5200
16	H 14637	11.2	5.1	6200
17	F 38761	11.8	4.6	4900
18	G 84276	11.7	4.7	5200
19	G 49228	13.4	5.0	6200
20	E 5104	9.7	4.2	7500
21	H 39751	12	4.6	6300
22	F 51934	11.2	4.2	5500
23	1804	9.8	5.8	6300
24	G 15162	10.6	4.2	6200
25	H 43447	12.9	5.2	11800
26	G 43549	12.3	5.0	8100
27	G 9292	10.5	5.1	7100
28	H 46418	11.5	4.2	5700
29	G 89313	12.6	4.5	7000
30	H 54244	12.7	5.6	6900
31	H 55033	11.3	4.6	5800
32	H 30254	12.4	4.7	6900
33	H 19105	11.7	5.1	5000
34	H 55355 / 1874	12.7	4.6	5200
35	1866	12.2	4.9	5100
36	H 43391	12	4.7	7300
37	H 34051	13.4	4.7	7000
38	H 68734	11.6	4.9	8500
39	H 70124	12.6	5.1	9400
40	1886	14	5.4	6700

STOOL CULTURE BEFORE TREATMENT

S. No	OP/IP No	AGE	SEX	PRESENTING ORGANISM
1	G 62467	10	FC	Shigella +
2	G 87627	8	FC	Shigella +
3	G 90640	8	MC	Shigella& E.coli+
4	G 91042	5	MC	Shigella+
5	F 63846	5	MC	Shigella+
6	F 33179	9	MC	Shigella+
7	F 10236	9	FC	Shigella+
8	F 23066	11	FC	Shigella+
9	G 98872	8	FC	Shigella& E.coli+
10	G 91964	12	MC	Shigella& E.coli+
11	G 91978	9	MC	Shigella+
12	H 4742	7	MC	Shigella+
13	G 27210	6	MC	Shigella+
14	E 48510	8	MC	E.coli & shigella+
15	H 14138	5	FC	Shigella+
16	H 14637	6	MC	Shigella+
17	F 38761	6	MC	Shigella+
18	G 84276	6	MC	Shigella+
19	G 49228	9	FC	E.coli+
20	E 5104	8	MC	Shigella+
21	H 39751	11	MC	Shigella+
22	F 51934	5	FC	Shigella,E.coli+
23	1804	5	FC	Shigella
24	G 15162	5	FC	Shigella+
25	H 43447	5	MC	Shigella+
26	G 43549	6	MC	E.coli+
27	G 9292	5	FC	E.coli+
28	H 46418	6	FC	Shigella+
29	G 89313	12	FC	E.coli+
30	H 54244	7	MC	Shigella+
31	H 55033	5	MC	Shigella+
32	H 30254	7	MC	E.coli+
33	H 19105	5	MC	E.coli+
34	H 55355 / 1874	12	MC	E.coli+
35	1866	10	MC	Shigella+
36	H 43391	9	FC	Shigella+
37	H 34051	12	MC	Shigella& E.coli+
38	H 68734	5	FC	E.coli+
39	H 70124	9	FC	E.coli+
40	1886	5	MC	Shigella+

Discussion

6.DISCUSSION

Kanakazhichal is a common pediatric problem.This disease has been clearly described in several siddha texts.Kanakazhichal mostly resembles like bacillary dysentery in modern system of medicine.This is characterised by passing loose stools with blood or mucous, fever, abdominal pain, tenesmus.

In this study several cases were treated at the out-patient department of P.G Kuzhandhai Maruthuvam at Ayothidoss pandithar hospital,National Institute of Siddha , Chennai and 4 cases were treated at the In-Patient ward P.G Kuzhandhai Maruthuvam , according to clinical features mentioned in siddha texts.Siddha methods of diagnosis were carried out and recorded in proforma.The diagnosis were confirmed and treated with trial drug 'ADHIMADHURA MAATHIRAI" and clearly observed.

The drugs which are mentioned in Siddha literature for the management of Kanakazhichal were selected and the study is conducted after the proposal was screened by the Screening committee of National Institute of Siddha and the trial was also approved by the Institutional Ethical Committee (IEC). The trial was registered in Clinical trial registry of India.

The trial drugs were prepared by the Author in the Gunapadam practical laboratory of National Institute of Siddha, after getting proper authentication of raw drugs from the Medicinal botany department at NIS, Chennai 47. The trial drug was prepared by the standard operating procedure as mentioned in the protocol.

The chemical analysis and physiochemical analysis of drugs were performed in biochemistry lab of NIS, and CSRI labarotaries, Chennai. The safety of the trial drug usage through chemical analysis was also ensured during the study. It revealed the presence of effective minerals.

The biochemical analysis of the trial medicine showed the presence of Tannic acid, Alkaloids, tyes of compounds, Aluminium, Ammonium.

The physio chemical analysis was done as preliminary evaluation of the trail drug. The method of measuring the moisture content in solid materials is loss on dryinugsg (LOD).Low moisture content is always desirable for higher stability of drugs. In Adhimadhura Maathirai showed ,Loss of drying at 105C was found to be 12.80% it falls in between the limit range(1-20%).so the moisture content shows the good stability of the drug Adhimadhura Maathirai.pH 4.40.

The ash value represents the purity of the drugs.The total ash includes both physiological ash, which is derived from the organic matter, and non physiological ash which is the residue of the extraneous matters like sand/soil, inorganic materials.The non physiologic ash is represented by acid soluble ash.The total ash in Adhimadhura Maathirai found to be 4.88%,and the acid insoluble ash to be 0.73%.The both ash value were under limits.The minimal level of acid insoluble ash shows the less inorganic residue and purity of the trial drug Adhimadhura Maathirai.

The extractive values helps to indicate the nature of chemical constituents present in the drug.The water soluble substance is polar in nature and the alcohol has the ability to dissolve non-polar substance.The water soluble extract value of Adhimadhura Maathirai is 7.15% and the Alcohol soluble extractive is 6.99%, its shows the possibility of water soluble constituents such as tannins, sugars, plant acids and mucilage, and alcohol soluble substance such as tannins, resins, and alkaloids to be present in the drug.As the drug Adhimadhura Maathirai having more water soluble constituents than alcohol soluble,it would be non polar.So the trial drug shows good absorption & intracellular distribution without possible of accumulation inside the cells.The good water solubility may rapid the drug absorption and action.

Strongly acidic nature of the drug can cause the harmful effects to the body.so the screening for the pH is important for the drug.It represents the chemical nature of the drug and the site of absorption of non polar drug.The pH of Adhimadhura Maathirai found to be 4.40 that is weakly acidic and safe in pH.The weakly acidic drugs are rapidly absorbed from stomach.So the trial drug Adhimadhura Maathirai can act rapidly on oral administration.Reducing sugar value is 4.41%.Total sugar value of Adhimadhura Maathirai is 14.75%.

Five organism have been studied for Antibacterial property of Adhimadhura Maathirai.Among the 5 organism Bacillus cereus were found to be suspectable in moderate dose level of Adhimadhura Maathirai(30mg/ml).And Streptococcus pyogens , Staphylococcus aureus, Pseudomonas aeruginosa were found to be less effective against trail drug(30mg/ml) in the study.

The patients were recruited for the trial based on inclusion and exclusion criteria and after getting the consent from the patient. 40 patients were included in this study. The 40 patients were treated in OPD and IPD of Ayothidoss Pandithar Hospital of National Institute of Siddha. Separate proforma was maintained for every patient. Progress chart was also maintained to monitor the clinical signs and symptoms of the disease.

The treatment was aimed at normalizing the deranged thodams and providing relief from symptoms. Before treatment the patients were advised to adapt lifestyle modifications such as oil bath weekly once and to follow good dietary regimen.

The patients were treated with trial drug ADHIMADHURA MAATHIRAI for 3 days. Patients were instructed to take the medicines regularly and advised to follow pathiyam and to avoid intake of contaminated foods if any. Patients were asked to visit the hospital on 4th day.

After completion of the study, the patients were advised to visit the Out-Patient ward of Department of Kuzhanthai Maruthuvam for 1 month for follow-up. The results observed during the study period were discussed by the author below.

Incidence with reference to age:

Out of 40 cases, 12 cases were between 5-6 years,6 cases were between 6-7 years,3 cases were between 7-8 years,5 cases were between 8-9 years,6 cases were between 9-10years, 2 cases were between 10-11years, and 6 cases were between 11-12 years.

Incidence wth reference to sex:

Among 40 cases 23 were male child and 17 were female child.

Incidence with reference to socioeconomic status:

Most of the patients(80%) belonged to middle class , 15% of patients belonged to poor socioeconomic status, 5% of patients belonged to rich socio economic status.

Distributions according to food habits:

According to food habits 73% of patients have mixed diet and 28% have vegetarian.

Incidence with reference to paruva kaalam:

According to this study the incidence of Kana Kazhichal during kaarkaalam was 3%, koothirkaalam 10%, munpanikaalam 28%, pinpanikkalam 23%, Ilaveeneerkaalam 25%, mudhuveneer kaalam 13%.

Incidence with reference to Thinai:

80% cases Neithal Nilam , 15% Marudha Nilam, 5% kurinji Nilam. This point slightly deviates from siddha conceps, that peoples of Neithal Nilam should free from the disease.This may be due to urbanization, industrialization, pollution, increased population and lack of personal hygiene.

Incidence with reference to mukkutram:

With reference to siddha texts mukkutram were analysed in the following pattern.

Vatham:

All the 40 cases showed derangement of abnanan,viyanan ana samanan that produces loose stools.rectal tenesmus,Abdominal discomfort etc..Udhanan was deranged in 25% of cases which produced nausea and vomiting.

Pitham:

90% the patients showed the derangement of Analam which produces Poor appetite.

Kabam:

All the patients showed derangement of Avalambagam ,90% of patients showed derangement of kiledhagam.

Incidence with reference to Ezhu udal kattugal:

Saaram were affected in all 40 cases, and 8% of cases were senner affected which produced generalized body weakness.

Incidence with reference to Envagai Thervugal:

According to this malam was affected in all 40 cases (100%)(Passing loose stools with mucous)

Naa was affected in 5% of cases(coated, dryness and ulcers in the tongue)

Incidence with reference to duration of illness:

Out of 40 cases, 50% of them complaints for 2days, 30% of them complaints for 3 days, 13% of them complaints for 4 days, 8%of them complaints for 7days.

Incidence with reference to clinical features:

Distribution according to clinical presentation in the clinical trial of the 40 patients loose stools reduced in 92% of cases, rumbling noise in the stomach reduced

in 100% of cases, Fever reduced in 95% of cases, abdomen pain reduced in 67% of cases.The clinical improvements were accurately noted and further follow up was made in outpatient department.

All the cases had Routine blood examination and stool culture were done. Most of the cases were normal blood investigation.Stool culture were done in all patients and most of the cases had shigella and Ecoli were present.

If the cases suffering from Kanakazhichal are not timely diagnosed and treated, it will leads to certain complications. They are ulceration of colon, weakened pulse,In modern system also the important complications explained are severe thirst, electrolyte loss, oliguria,and rectal prolapse etc.

In order to prevent the complications in the patients with KanaKazhichal and treat the patients with the trial medicine "Adhimadhura Maathirai" was given in hot water two times a day for 3 days.

All the patients were strictly advised to follow pathiyam.They were also advised to follow personal hygiene and other preventive measures.Satisfactory improvement was reported within 3 days of commencement of the treatment.

The clinical symptoms score of Adhimadhura Maathirai, before and after treatment were3.9 ± 2.13 and 0.35 ± 1.7 respectively.Which is statistically significant P <0.0001 t-value =23.4015.Out of 40 cases signs and symptoms were completely relieved in 90% of cases. Symptoms were reduced in 10% of cases.The results were based on the clinical symptoms.

This study evaluates the effect of "*ADHIMADHURA MAATHIRAI*" in relieving the symptoms of *KANAKAZHICHAL*.

Summary

7.SUMMARY

Childrens attending the OPD of NIS having the compliants of *KanaKazhichal* diagnosed clinically and the patients were observed for clinical diagnosis, laboratory diagnosis. Classical symptoms of *KanaKazhichal* emphasis with the symptoms of Bacillary dysentery like Passing loose stools with blood or mucus, fever, abdominal pain, tenesmus.

The Clinical study has been approved by IEC of NIS, approval No:NIS/IEC/8-14/22-26-08-2014.The trial registred in Clinical trial Registry of India with Reg .No.CTRI/2016/04/006787. The Authentication of ingredients of the trial drug was done obtained from Medicinal Botanist, National Institute of Siddha, Chennai. Purification of raw drugs and preparation of trial drug was done at Gunapadam Laboratory, Department of Gunapadam, NIS Chennai.

Chemical Qualitative analysis of trial drug was done in Biochemistry laboratory, Department of Biochemistry, National Institute of Siddha, Chennai.The Laboratory investigations were done accordingly.

Clinical diagnosis of Kana Kazhichal was done on the basis of clinical features described in Kuzhandhai Maruthuvam,Siddha maruthuvam, Noi naadal and Noi mudhal naadal thiratu etc.

The etiology and clinical features of Kana Kazhichal were correlated with the etiology and clinical features of Bacillary dysentery.

Dehydrated childrens, childrens having lactose intolerance, ulcerative colitis, chronic diarrhea and child need for emergency treatment were excluded for this study.

Siddha system of clinical methods like Envagai thervugal, Neerkuri, Neikuri were carried out in all the patients and recorded.Routine blood examination and stool culture were done in all the patients.

The chemical analysis of the trial medicine showed the presence of tannic acid, alkaloids, type of compound, ammonium,aluminium.

The physio chemical analysis of the trial drug showed the presence of Reducing sugar 4.41%, Disintegration test 29mins, Total sugar 14.75%,Loss of drying at 105C 12.80%.pH 4.40.

The Antibacterial study of the trail drug Adhimadhura Maathirai showed effective inhibitory actions against shigella,less effective in Streptococcus pyogens , Staphylococcus aureus, Pseudomonas aeruginosa.

The trail medicine Adhimadhura Maathirai was given internally two times a day for 3days with hotwater for the clinical treatment and management of KanaKazhichal.The dosage of the trail drug is 1 tablet(580mg).

The observation made during the clinical study showed that the trial drug Adhimadhura Maathirai was clinically effective for Kanakazhichal.

The parents and children were adviced to follow the preventive measures and to lead a hygienic life.

The clinical efficacy of the drug was analyzed statistically on all the symptoms mentioned in the assessment criteria. The observation made during the clinical study showed that the trail drug *Adhimadhura Maathirai* was clinically effective.

The mean and standard deviation of KANAKAZHICHAL Before and After treatment were 3.9 ± 2.13 and 0.35 ± 1.7 respectively.Which is statistically significant P <0.0001 t-value =23.4015

The reduction of clinical symptoms after the treatment is significant (p <0.0001). The reduction in the symptoms is 91 % from the start of the treatment.

Conclusion

8.CONCLUSION

All the fourty out patient and in-patient childrens in the P.G Kuzhandhai Maruthuvam department , National Institute of Siddha,Chennai-47 with Kanakazhichal were treated with Adhimadhura Maathirai 1 tablet(580mg) with hotwater two times a day for 3 days.

No adverse effects were noticed during the treatment period.The trial drug Adhimadhura Maathirai is purely herbal, easily available drugs and harmless to childrens.

The method of preparation is easy and the cost is comparatively economical.

The drugs had got Anti bacterial activity.clinical results were found to be good in 90% of cases and moderate results were found in 10% of cases.

Because of the encouraging results clinically , the study may be undertaken with same medicine in a large number of cases and it may through new lights to the young researchers and academic community to develop good management procedure for the treatment of “Kanakazhichal.

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Annexure

ANNEXURES:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL,
CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF ADHIMADURA MAATHIRAI FOR KANAKAZHICHAL (Bacillary Dysentry) IN CHILDREN.

Form 1- SCREENING

1. S.I. No:	2. OP/ IP No:	3.Name:
4. Age:	5.Sex:	6.Date of Enrollment:
7. Date of completion:	8.Informant:	9.Reliablity:

INCLUSION CRETERIA:	YES	NO
Age: between 5-12 years	☐	☐
Presence of mucous / blood in stools	☐	☐
Fever	☐	☐
Tenesmus	☐	☐
Abdominal cramps	☐	☐
Rumbling in the intestine	☐	☐
EXCLUSION CRITERIA:		
High grade fever	☐	☐
Profuse dehydration	☐	☐
Extra intestinal complication	☐	☐
Chronic diarrhoea	☐	☐

Signature of Lecturer: Signature of Principal Investigator

Signature of HOD:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

CHENNAI – 600047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CONSENT FORM

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all the details about the study in the terms readily understood by the parent/guardian

Signature _____

Date _____

Name _____

CONSENT BY PARENT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my son/daughter's body functions.

I am aware of my right to opt my son/daughter out of the trail at any time during the course of the trail without having to give the reasons for doing so.

I, exercising my free power of choice, here by give my consent to include my son/daughter as a subject in the clinical trial of **"ADHIMADURA MAATHIRAI"** for the treatment of "**KANAKAZHICHAL"**

Date : _____ Signature

Name _____

Date : Signature of witness _____

Name _____

தேசிய சித்த மருத்துவ நிறுவனம்
அயோத்திதாச பண்டிதர் மருத்துவமனை சென்னை-47
குழந்தை மருத்துவத்துறை

அதிமதுர மாத்திரை பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்வு

ஒப்புதல் படிவம்
ஆய்வாளரால் சான்றளிக்கப்பட்டது.

நான் இந்த மருத்துவ ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளியின் பெற்றோருக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதி அளிக்கிறேன்.

தேதி: கையொப்பம்:
இடம்: பெயர்:

நோயாளியின் பெற்றோர் ஒப்புதல் படிவம்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும்,மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறைப் பற்றியும்,இந்த மருத்துவத்தை தொடர்ந்து எனது குழந்தையின் உடல் இயக்கத்தைக் கண்காணிக்கவும்,அதனைத் பாதுகாக்க பயன்படும் மருத்துவ ஆய்வுக்கூடப் பரிசோதனைகள் பற்றியும் திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது காரணம் எதுவும் கூறாமல் எப்போது வேண்டுமானாலும் என் குழந்தையை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கிறேன்.

நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு கணகழிச்சல் நோய்க்கான அதிமதுர மாத்திரை பரிகரிப்புத் திறனை கண்டறியும் மருத்துவ ஆய்வுக்கு எனது குழந்தையை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: பெற்றோர் பெயர்

இடம்: கையொப்பம்:
சாட்சிக்காரர்பெயர்:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL,CHENNAI – 600047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF ADHIMADHURA MAATHIRAI FOR KANAKAZHICHAL (Bacillary Dysentry) IN CHILDREN

FORM 3 -CASE REPORT FORM

1.HISTORY TAKING **Demographic data**

OP/IP No.	Visit Date : (__/__/____)
Name :	
Age : ☐ Year ☐ Month	Sex Male ☐ Female ☐
Father/ Mother /Guardian Name :	
Fathers Occupation :	
Fathers Monthly Income :	
Religion :	☐ Hindu ☐ Christian ☐ Muslim ☐ Others
Socioeconomic Status :	☐ Rich ☐ Middle class ☐ Poor
Informant :	

Postal Address

Contact No :

1. **Complaints and Duration**

2. **Present illness**

3.History of Past Illness

History /Symptoms/Signs	**Yes**	**No**	**If, Yes Details**
Any Similar Complaints	☐	☐	_____
Hospitalization	☐	☐	_____
	☐	☐	
Any other			_____

Family History

Any Hereditary/ Familial Disease Yes ☐ No ☐

If Yes, Details--------

Immunisation History

Proper Immunization given Yes ☐ No ☐

Food habits:

1. Veg ☐ 2. Non-Veg ☐

2. **Habits:**

1. Picca ☐ ☐
2. Nail biting ☐ ☐
3. Thumb sucking ☐ ☐
4. Bed wetting ☐ ☐

General Examination

1. Pallor YES ☐ NO ☐
2. Jaundice YES ☐ NO ☐
3. Cyanosis YES ☐ NO ☐
4. Clubbing YES ☐ NO ☐
5. Pedal oedema YES ☐ NO ☐
6. Lymph adenopathy YES ☐ NO ☐

<u>Vital signs:-</u>

1. Pulse rate / mint

2. Heart rate / mint

3. Respiratory Rate / mint

4. Temperature

Anthropometry:-

Height

Weight

SYSTEMIC EXAMINATION

Gastro intestinal system

a) Inspection:

Shape / symmetry : ☐ Normal ☐ Abnormal

Abdominal Distension : Absent ☐ Present ☐

Prominent veins: Present ☐ Absent ☐

Hernia : present ☐ Absent ☐

Visible peristalsis : present ☐ Absent ☐

b) PALPATION:

Tenderness Yes ☐ No ☐

If yes_____

Organomegaly

Liver ☐

Spleen ☐

Kidney ☐

Aorta ☐

Bladder ☐

C) Percussion:

Percussion of Abdomen : Normal ☐

Hyper resonance ☐

Dullness ☐

D) Auscultation:

Bowels sounds

Normal ☐ decreased ☐ increase ☐

E) Rectal Examination :

Ulcer Yes ☐ ☐o

Redness Yes ☐ ☐

Other systems:	Normal	Affected
Cardio vascular system:	☐	☐
Respiratorysystem	☐	☐
Musculo skeletal system:	☐	☐

Clinical assessment:	**YES**	**NO**
Increased frequency of mucous or blood in stools	☐	☐
Fever	☐	☐
Tenesmus	☐	☐
Rumblings in the intestine	☐	☐
Abdominal pain	☐	☐

Nilam:-

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Paalai ☐

KaalaIyalbu:-

Kaarkalam	☐	Koothirkaalam	☐	Munpanikaalam	☐
Pinpanikaalam	☐	Illavenirkaalam	☐	Muthuvenirkaalam	☐

Yaakai

Vatham	☐	VathaPitham	☐	VathaKabam	☐
Pitham	☐	Pithavatham	☐	PithaKabam	☐
Kabam	☐	KabaVatham	☐	KabaPitham	☐

Gunam

Sathuvam ☐ Rasatham ☐ Thamasam ☐

Pori / Pulangal

	Normal	Affected	Normal	Affected	Remarks
Mei / unarvu	☐	☐	☐	☐	
Vaai / suvai	☐	☐	☐	☐	
Kan / parvai	☐	☐	☐	☐	
Mooku / natram	☐	☐	☐	☐	
Sevi / oli	☐	☐	☐	☐	

Kanmendhirium / Kanmavidayam

	Normal	Affected	Normal	Affected
Remarks	☐	☐	☐	☐
Kai / dhanam	☐	☐	☐	☐
Kaal / ghamanam	☐	☐	☐	☐
Vaai / vaku				
Eruvai / visarkam	☐	☐	☐	☐
Karuvai / anantham	☐	☐	☐	☐

UyirThathukkal

Vatham:

	Normal	Affected	Remarks
Pranan	☐	☐	
Abanan	☐	☐	

Viyanan	☐	☐
Uthanan	☐	☐
Samanan	☐	☐
Nagan	☐	☐
Koorman	☐	☐
Kirukaran	☐	☐
Devathathan	☐	☐
Dhanajeyan	☐	☐

Pitham

	Normal	Affected	Remarks
Analam	☐	☐	
Ranjagam	☐	☐	
Saathagam	☐	☐	
Alosagam	☐	☐	
Prasagam	☐	☐	

Kabam

	Normal	Affected	Remarks
Avalambagam	☐	☐	
Kilethagam	☐	☐	
Pothagam	☐	☐	
Tharpagam	☐	☐	
Samthigam	☐	☐	

Udalthathukkal

	Normal	Affected	Remarks
Saaram	☐	☐	
Senneer	☐	☐	
Oon	☐	☐	
Kozhuppu	☐	☐	
Enbu	☐	☐	
Moolai	☐	☐	
Sukilam / Suronitham	☐	☐	

EnvagaiThervugal

	Normal	Affected	Remarks
Naa			
Niram	☐	☐	
Thanmai	☐	☐	
Suvai	☐	☐	
Niram	☐	☐	
Mozhi	☐	☐	
Vizhi			
Niram	☐	☐	

Thanmai ☐ ☐

Parvai ☐ ☐

Sparisam ☐ ☐

Malam

Niram Normal ☐ Affected ☐

Nurai Normal ☐ Affected ☐

Elagal Yes ☐ No ☐

Erugal Yes ☐ No ☐

Moothiram

Neerkuri: Niram Normal ☐ Affected ☐

Edai Normal ☐ Affected ☐

Nurai Normal ☐ Affected ☐

Manam Normal ☐ Affected ☐

EnjalNeikuri Normal ☐ Affected ☐

Neikuri:

Vatham ☐

Pitham ☐

Kabam ☐

Others ☐

<u>Naadi:</u>

<u>ThaniNadi</u>

Vadham ☐ pitham ☐ kabam ☐

ThonthaNadi

Vathapitham ☐ Pitha vatham ☐ Pitha kabam ☐ Kabapitham ☐

Vatha kabam ☐ Kaba vatham ☐

Mukkutra Nadi

Admitted to trial: 1.Yes ☐ 2. No ☐

If yes, S. No: 1.IP ☐ 2.OP ☐

Diagnosis:

DRUGS ISSUED:_____

Date : _____

Station : _____

2.CLINICAL ASSESSMENT

S.NO	**CLINICAL SYMPTOMS**	**1st day**	**4th day**
1.	Increased frequencyof mucous in stools/blood with mucous		
2.	Fever		
3	Tenesmus		

4	Rumbling noise in the intestine		
5	Abdominal cramps		

3.LABORATORY INVESTIGATIONS :

Stool culture:

ROUTINE BLOOD INVESTIGATIONS		NORMAL VALUES	BEFORE TREATMENT Date:	AFTER TREATMENT Date:
Hb (gms%)		11.5 – 14.5		
T.RBC (milli /cu.mm)		4-4.9		
DIFFERENTIAL COUNT (%)	Polymorphs	40-75		
	Lymphocytes	28-48		
	Monocytes	3-6		
	Eosinophils	0-3		
	Basophils	0-1		

Date: Signature of Principal Investigator

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF ADHIMADURA MAATHIRAI FOR KANAKAZHICHAL (Bacillary Dysentry) IN CHILDREN

WITHDRAWAL FORM

1. S.L. No:	2. OP/ IP No:	3.Name:
4.Age:	5.Sex:	6.Date of Enrollment:
7. Date of completion:	8.Informant:	9.Reliablity:

Date of withdrawal from trial :

Reason(s) for withdrawal : Yes/ No

Long absence at reporting : Yes/ No

Irregular treatment : Yes/ No

Shift of locality :Yes/ No

Complication adverse reactions if any : Yes/ No

Exacerbation of symptoms : Yes/ No

Patient not willing to continue : Yes/ No

Date: Signature of Principal Investigator

1. Patient / consumer identification (please complete or tick boxes below as appropriate)

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

Reporting Form for Suspected Adverse Reactions to Siddha Drugs

Please note: i. **all** consumers / patients and reporters information will remain confidential.
ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

Peripheral Center code: State:

<table>
<tr><td>Name</td><td>Father name</td><td rowspan="2">Patient / Record No.</td></tr>
<tr><td>Ethnicity</td><td>Occupation</td></tr>
<tr><td colspan="2" rowspan="2">Address
Village / Town
Post / Via
District / State</td><td>Date of Birth / Age:</td></tr>
<tr><td>Sex: Male / Female
Weight :
Degam:</td></tr>
</table>

2. Description of the suspected Adverse Reactions (please complete boxes below)

Date and time of initial observation		Season:
Description of reaction		Geographical area:

3. List of all medicines / Formulations including drugs of other systems used by the patient during the reporting period:

Medicine	**Daily dose**	**Route of administration & Vehicle – Adjuvant**	**Date**		**Diagnosis for which medicine taken**
			Starting	**Stopped**	
Siddha					
Any other system of medicines					

4. Brief details of the Siddha Medicine which seems to be toxic :

Details	Drug – 1	Drug – 2	Drug - 3
a) Name of the medicine			
b) Manufacturing unit and batch No. and date			

c) Expiry date			
d) Purchased and obtained from			
e) Composition of the formulation / Part of the drug used			

b) Dietary Restrictions if any

c) Whether the drug is consumed under Institutionally qualified medical supervision or used as self medication.

d) Any other relevant information.

5. Treatment provided for adverse reaction:

6. The result of the adverse reaction / side effect / untoward effects (please complete the boxes below)

Recovered:	Not recovered:	Unknown:	Fatal:	If Fatal Date of death:

Severe: Yes / No.	Reaction abated after drug stopped or dose reduced:
	Reaction reappeared after re introduction:

Was the patient admitted to hospital? If yes, give name and address of hospital	

7. Any laboratory investigations done to evaluate other possibilities? If Yes specify:

8. Whether the patient is suffering with any chronic disorders?

Hepatic Renal Cardiac Diabetes Malnutrition

Any Others

9. H/O previous allergies / Drug reactions:

10. Other illness (please describe):

11. Identification of the reporter:

Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer / Distributor / Supplier / Any others (please specify)
Name:
Address:
Telephone / E – mail if any :

Signature of the reporter: **Date:**

Please send the completed form to:

Name & address of the RRC-ASU / PPC-ASU

The Director

National Institute of Siddha,

(Pharmacovigilance Regional Centre For Siddha Medicine),

Tambaram Sanatorium, Chennai-600 047.

☏ (O) 044-22381314 Fax : 044 – 22381314

Website : www.nischennai.org

Email: nischennaisiddha@yahoo.co.in

* * * *

NATIONAL INSTITUTE OF SIDDHA

AYOYHIDOSS PANDITHAR HOSPITAL, CHENNAI-600047

DEPARTMENT OF KUZHANTHAI MARUTHUVAM

A CLINICAL EVALUATION OF ADHIMADURA MAATHIRAI FOR THE TREATMENT OF KANAKAZHICHAL (BACILLARY DYSENTRY) IN CHILDREN.

1.SL.NO:	2. OP/IP NO:	3.Name:
4.Age:	5.Sex:	6.Date of enrollment
7.Informant:	8.Reliablity:	

ASSENT FORM (BY PATIENT)

I, Understand that my parents (mom and dad)/guardian have /has given permission (said it's okay) for me to take part in a project about Kanakazhichal doing by Dr.D.SARANYA

I am taking part because I want to take part. I have been told that I can stop at any time I want to do so and nothing will happen to me if I want to stop.

Date Signature of the patient(child).

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF ADHIMADURA MAATHIRAI FOR KANAKAZHICHAL(Bacillary Dysentry) IN CHILDREN

ADVERSE REACTION

Sl.No :

OPD/ IPD No :

Name :

Age :

Sex :

OPD/ IPD No :

Registration No :

Date of trial commencement :

Date of withdrawal from trial :

Description of adverse reaction :

Date: Signature of Principal Investigator

சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம், அரும்பாக்கம், சென்னை - 600106
सिद्ध केन्द्रीय अनुसंधान संस्थान, अरुम्बाक्कम, चेन्नै - 600106
Siddha Central Research Institute
(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India)
Arumbakkam, Chennai – 600106
[Ph: 044-26214925, 26214809, Fax: 26214809, Email: crisiddha@gmail.com, Web: www.siddhacouncil.com]

01.3.16

Name of the student: Dr. D. Saranya, II Year Kuzhandai Maruthuvam,

National Institute of Siddha, Chennai-47.

PHYSICO-CHEMICAL ANALYSIS OF ADHIMATHURA MATHIRAI

S.No	Parameter		Mean
1.	Loss on Drying at 105°C	:	12.80 %
2.	Total Ash	:	4.88 %
3.	Acid insoluble Ash	:	0.73 %
4.	Water Soluble Extractive	:	7.15 %
5.	Alcohol Soluble Extractive	:	6.99 %
6.	pH	:	4.40
7.	Disintegration Test	:	29 min.
8.	Average weight of 20 tablets	:	0.3015 g
9.	Reducing sugar	:	4.41 %
10.	Total sugar	:	14.75 %

(R. Shakila)
Research Officer (Chemistry)

1/3/16
(Dr. P.Sathiyarajeswaran)
Assistant Director (Scientist 2)-I/c

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

CERTIFICATE OF BOTANICAL AUTHENTICITY

Certified that the following plant drugs used in the Siddha formulation **"Adhimadhura maathirai"** (Internal) for the treatment of **Kanakazhichal** (Bacillary dysentery) taken up for Post Graduation Dissertation studies by **Dr.D.Saranya**, M.D.(S), II year, Department of Kuzhandhai Maruthuvam, 2015, are identified and authenticated through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology, Micromorphology and Taxonomical methods as

Glycyrrhiza glabra Linn. (Fabaceae), Root
Aconitum heterophyllum Wall. (Ranunculaceae), Root
Myristica fragrans Houtt. (Myristicaceae), Seed
Punica granatum Linn. (Punicaceae), Flower and fruit
Cuminum cyminum Linn. (Apiaceae), Fruit

Certificate No: NISMB1892015

Date: 27-08-2015

27/8/15
Authorized Signatory
Dr. D. ARAVIND, M.D.(S),M.Sc.,
Assistant Professor
Department of Medicinal Botany
National Institute of Siddha
Chennai - 600 047. INDIA

The Tamil Nadu Dr.M.G.R. Medical University

#69, Anna salai, Guindy, Chennai-600 032.

This certificate is awarded to

Dr./~~Mr.~~/~~Ms.~~ D. SARANYA

for participating as ~~Resource Person~~ / Delegate in the Sixteenth Workshop on

"Research Methodology & Biostatistics"

for AYUSH Post Graduates & Researchers

Organised by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University from 04.08.2014 to 08.08.2014

Dr. N. KABILAN M.D. (Siddha)	Dr. JHANSI CHARLES, M.D.	Prof. Dr. D. SHANTHARAM, M.D., D.Diab.,
Reader, Dept. of Siddha	Registrar	Vice-Chancellor

NATIONAL INSTITUTE OF SIDDHA
राष्ट्रीय सिद्ध संस्थान

Department of AYUSH- MINISTRY OF HEALTH & FAMILY WELFARE
आयुष विभाग - स्वास्थ एवं परिवार कल्याण मंत्रालय
GOVERNMENT OF INDIA-भारत सरकार

TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सनटोरियम चेन्नई -600 047
फ़ोन\Tele : 044-22411611 फैक्स\Fax : 22381314
ईमेल: nischennaisiddha@yahoo.co.in वेब :www.nischennai.org

F.No.NIS/6-20/IEC/14-15 Dt: 25.09.14

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr.D.Saranya, P.G.Student, Kuzhandhai Maruthuvam	
Protocol title: A clinical evaluation of Adhimadhura mathirai a Siddha drug for Kanakazhichal (Bacillary dysentery) in children	
Documents filed	1) Protocol, 2) Data Collection forms 3) Patient Information Sheet 4) Consent form 5) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	**Yes**
Informed consent documents	**Yes**
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/8-14/22 - 26-08-2014**

We approve the trial to be conducted in its presented form.

The institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent.

Chairman **Member Secretary**

Clinical Trial Details (PDF Generation Date :- Wed, 29 Jun 2016 10:45:38 GMT)

CTRI Number	CTRI/2016/04/006787 [Registered on: 01/04/2016] - **Trial Registered Retrospectively**
Last Modified On	30/03/2016
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Siddha
Study Design	Single Arm Trial
Public Title of Study	A clinical trial for bacillary dysentry in children
Scientific Title of Study	Clinical evaluation of Adhimadhura Mathirai a siddha drug for kanakazhichal in children

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	D SARANYA
Designation	PG SCHOLAR
Affiliation	NATIONAL INSTITUTE OF SIDDHA
Address	NATIONAL INSTITUTE OF SIDDHA TAMBARAM SANATORIUM CHENNAI NATIONAL INSTITUTE OF SIDDHA TAMBARAM SANATORIUM CHENNAI Chennai TAMIL NADU 600047 India
Phone	9597907472
Fax	
Email	sarosaranya13@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Prof Dr Kalyana Sundaram
Designation	Head of the Department Kuzhandhai Maruthuvam
Affiliation	NATIONAL INSTITUTE OF SIDDHA
Address	NATIONAL INSTITUTE OF SIDDHA TAMBARAM SANATORIUM CHENNAI NATIONAL INSTITUTE OF SIDDHA TAMBARAM SANATORIUM CHENNAI Chennai TAMIL NADU 600047 India
Phone	9444946270
Fax	
Email	kalyas53@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	DrKSuresh
Designation	Lecturer of Kuzhadhai Maruthuvam
Affiliation	NATIONAL INSTITUTE OF SIDDHA
Address	NATIONAL INSTITUTE OF SIDDHA TAMBARAM SANATORIUM CHENNAI NATIONAL INSTITUTE OF SIDDHA TAMBARAM SANATORIUM CHENNAI Chennai TAMIL NADU 600047

	India
Phone	9962571137
Fax	
Email	drsureshherbal@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> self

Primary Sponsor

Primary Sponsor Details	
Name	NATIONAL INSTITUTE OF SIDDHA
Address	DEPARTMENT OF KUZHANDHAI MARUTHUVAM NATIONAL INSTITUTE OF SIDDHA TAMBARAM SANATORIUM CHENNAI
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr D Saranya	NATIONAL INSTITUTE OF SIDDHA	DEPARTMENT OF KUZHANDHAI MARUTHUVAM NATIONAL INSTITUTE OF SIDDHA TAMBARAM SANATORIUM CHENNAI 600047 Chennai TAMIL NADU	9597907472 sarosaranya13@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional ethics committee	Approved	26/08/2014	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	•Increase in frequency of mucous in stools •Rumblings in the intestine. •mild fever and Abdominal cramps

Intervention / Comparator Agent

Type	Name	Details
Intervention	Adhimathura Maathirai	thoodulangai alavu(580 mg) b.d. orally 5-12 years (3 days)
Comparator Agent	NA	NA

Inclusion Criteria

Inclusion Criteria	
Age From	5.00 Year(s)
Age To	12.00 Year(s)
Gender	Both
Details	Increased frequency of mucous in stools Rumblings in the intestine. mild fever and chills history of abdominal pain

Exclusion Criteria

Exclusion Criteria	
Details	Continous fever for few days Signs of profuse dehydration. Extra intestinal complication. Exacerbation of chronic diarrhea in inflammatory bowel disease or malabsorption.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
Clinical symptoms releived	Clinical symptoms releived

Secondary Outcome

Outcome	Timepoints
clinical efficacy of the trial drug	nil

Target Sample Size	**Total Sample Size=**40 **Sample Size from India=**40
Phase of Trial	Phase 2
Date of First Enrollment (India)	18/06/2015
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	nil
Brief Summary	To evaluate the therapeutic efficacy of siddha poly herbal formulation adhimadhura mathirai in the treatment of kana kazhichal...

POONGA BIOTECH RESEARCH CENTRE

No.10/58, Kamala Nehru Nagar, 1st Street, Choolaimedu, Chennai - 600 094.
Ph : 044 - 23634289, Website : www.poongabiotech.com

Dr. B. Janarthanam
Chief Scientist

4.7.2016

To whomsoever it may concern

This is certify that Dr. D. Saranya, National Institute of Siddha, Tambaram Sanatoruim, Chennai, Tamil Nadu 600047 has carried out the following work in our centre.

Anti-Baterial activity of Adhimadhura mathirai

B. Janarthanam

Dr. B. Janarthanam